Trilateral Project B3b

Mutual understanding in search and examination

Report on Comparative study on biotechnology patent practices

Theme: Comparative study on “reach-through claims”

San Francisco, California
November 5-9, 2001

European Patent Office

Japan Patent Office

United States Patent and Trademark Office

Trilateral Project B3b

Mutual understanding in search and examination

Report on Comparative study on biotechnology patent practices

Theme: Comparative study on “reach-through claims”

1. Introduction

A recent phenomenon in the field of biotechnology has been the filing by applicants of an increasing number of "reach-through claims," (claims to future inventions based on currently disclosed inventions). These include claims directed to candidate compounds that might be identified by using basic screening methods and to downstream uses of such candidate compounds. For example, the Offices are seeing an increasing number of applications that include claims drawn to include all the possible pharmaceutical candidate compounds identified by assaying, and claims to methods of using such candidate compounds that might be considered to be beyond the scope of the subject matter contributed by the inventor.

Given the widespread reach for downstream inventions, there is a need to compare how the patentability standards and examination strategies in the Trilateral Offices apply to these types of claims.

Based upon this need, the three Offices agreed to conduct a comparative study to enhance mutual understanding concerning the examination of "reach-through claims."

2. Provisions

Applicable Sections / Articles of Respective Patent Laws

	Industrial Applicability / Utility	Enablement / Support / Sufficiency / Written Description and Clarity
USPTO	101	112
EPO	57	83, 84
JPO	29 (1)	36 (4) (6)

USPTO

35 U.S.C. § 101: Utility

To comply with 35 U.S.C. § 101, the claimed invention must have at least one specific, substantial, and credible utility that is either asserted in the specification or is well-established.

35 U.S.C. § 112, first paragraph: Enablement

To comply with the enablement requirement of 35 U.S.C. § 112, first paragraph, the specification must enable one skilled in the art to make and use the claimed invention without undue experimentation. Factors to be considered in determining whether any necessary experimentation is "undue" include the breadth of the claims, the nature of the invention, the state of the prior art, the level of ordinary skill in the art, the level of predictability in the art, the amount of direction provided by the inventor, the presence or absence of working examples, and the quantity of experimentation needed to make or use the invention based on the content of the disclosure.

35 U.S.C. § 112, first paragraph: Written Description

To comply with the written description requirement of 35 U.S.C. § 112, first paragraph, a patent specification must describe the claimed invention in sufficient detail such that one skilled in the art would reasonably conclude that the inventor had possession of the claimed invention. An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention. Possession may be shown in a variety of ways including description of an actual reduction to practice, or by showing that the invention was "ready for patenting" such as by the disclosure of drawings or structural chemical formulas that show that the invention was complete, or by describing distinguishing identifying characteristics sufficient to show that the applicant was in possession of the claimed invention.

35 U.S.C. § 112, second paragraph: Claim Definiteness

To comply with the claim definiteness requirement of 35 U.S.C. § 112, second paragraph, each claim must particularly point out and distinctly claim the subject matter which the applicant regards as his or her invention. A claim is definite if one skilled in the art would be reasonably apprised of the scope of the claim when the claim is read in light of the specification.

EPO

EPC Art.57: Industrial Application

(Guidelines C-IV 4.6) "In general it is required that the description of a European patent application should, where this is not self-evident, indicate the way in which the invention is capable of exploitation in industry. In relation to sequences and partial sequences of genes this general requirement is given specific form in that the industrial application of a sequence or a partial sequence of a gene must be disclosed in the patent application. A mere nucleic acid sequence without indication of a function is not a patentable invention..."

EPC Art.83: Sufficiency of disclosure

(Art.83) "The European patent application must disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art"

(Guidelines C-II, 4.9) "The application must contain sufficient information to enable the person skilled in the art, using his common general knowledge, to perform the invention over the whole area claimed without undue burden and without needing inventive skill."

EPC Art.84: Clarity and Support

(Art. 84) "The claims shall define the matter for which protection is sought. They shall be clear and concise and be supported by the description."

(Rule 29(1)) "The claims shall define the matter for which protection is sought in terms of the technical features of the invention"

(Guidelines C-III 6.3) "In order to comply with the requirement of Art. 84, there must be sufficient support of technical character in the description that allows to extend the particular teaching of the description to the whole field claimed. "

JPO

Japanese Patent Law Sect. 29, First Sentence: Industrially Applicable Inventions

(Guidelines Part VII,Chap.2, 1.3.1) "Inventions ... whose utility is not described in a specification or cannot be inferred, do not meet the requirements set forth in the first sentence in Section 29(1) of the Patent Law."

Japanese Patent Law Sect. 36(6): Clarity of Claims

(Guidelines Part VII, Chap. 2, 1.1.1) "According to Section 36(6)(ii) of the Patent Law, the invention for which a patent is sought shall be clear, therefore, scope of claim shall be described so that an invention is clearly identified on the basis of statements of each claim."

Japanese Patent Law Sect. 36(4) :Description, Enablement

(Guidelines Part VII, Chap. 2, 1.1.2.1) "Section 36(4) of the Patent Law states that "the detailed description of the invention shall be stated....in such a manner sufficiently clear and complete for the invention to be carried out by a person having ordinary skill in the art to which the invention pertains." ...For an invention of a product, the definition of "being able to carry out the invention" is to make and use the product..."

3. Questions

A) Questions Common to All Cases

1. Do the following claims satisfy clarity, enablement, support and written description requirements? If not, explain why.

2. Do the following claims satisfy the industrial applicability or utility requirements? If not, explain why.
3. If there are any comments on the kind of evidence, argument, and/or claim amendment that may overcome any rejection for failure to satisfy the requirement of 1 and/or 2 above, please state them.

B) The Cases

Case 1:

Outline of the Specification:

The application describes the isolation of a protein (SEQ ID NO:1) which meets the novelty and inventive step (non-obviousness) requirements. Based upon the disclosed homology to known R-receptor amino acid sequences, there is no reason to doubt that the claimed receptor represents a new member of this protein family. The application further discloses that different R-receptors are important in a wide variety of physiological processes, but does not disclose any ligand for the receptor of SEQ ID NO: 1 or any particular biological or biochemical process in which this receptor is involved. The patent application specification includes a general description of a series of screening procedures commensurate in scope with those recited in the claim. However, the application discloses no working examples wherein agonists of this receptor, i.e., compounds activating this receptor, are identified using the disclosed screening procedure.

Furthermore, although the receptor of SEQ ID NO: 1 was expressed in an animal cell, antibodies that recognize the receptor were not actually produced.

Claims:

1. An isolated and purified receptor the sequence of which consists of SEQ ID NO: 1.

2. A method of identifying an agonist of the receptor of claim 1 comprising:
   preparing a candidate compound,
   contacting a cell which expresses said receptor on its surface with said candidate compound, and
   determining whether said candidate compound activates the receptor of claim 1,
   wherein a compound that activates the receptor of claim 1 is an agonist of said receptor.

3. An isolated and purified receptor agonist identified by the method of claim 2.

4. (EPO) Use of a receptor agonist for the manufacture of a medicament for treating a disease treatable by said agonist, wherein said receptor agonist is identified by the method of claim 2.

(USPTO) A method for the treatment of disease treatable by the agonist of claim 2, comprising administering to a host in need thereof a therapeutically effective amount of the agonist identified by the method of claim 2.
(JPO) Composition comprising a receptor agonist for use in treating a disease treatable by said agonist, wherein said receptor agonist is identified by the method of claim 2, as an active ingredient.

5. A monoclonal antibody which recognizes the receptor of claim 1.

Case 2

Outline of Specification:

The application describes the isolation of a receptor (SEQ ID NO: 2) which meets the novelty and inventive step (non-obviousness) requirements as well as methods of screening for compounds that activate this receptor. The application further discloses that the receptor is useful for the treatment of obesity.

The relationship between the absence of this receptor and the occurrence of obesity is determined by experimental measures, and there is no doubt that the activation of this receptor can treat or inhibit obesity.

The patent application specification includes a general description of a series of screening procedures commensurate in scope with those recited in the claims. The description also teaches a method of measuring the biochemical and binding activity of this specific receptor, and there is no doubt that these activities can be measured. However, the application discloses no working examples wherein agonists of this receptor, i.e., compounds activating this receptor, are identified using the disclosed screening procedure.

Furthermore, although the receptor of SEQ ID NO: 2 was expressed in an animal cell, antibodies that recognize the receptor were not actually produced.

Claims:

1. An isolated and purified receptor the sequence of which consists of SEQ ID NO: 2.

2. A method of identifying an agonist of the receptor of claim 1 comprising:
preparing a candidate compound,
contacting a cell which expresses said receptor on its surface with said candidate compound, and
determining whether said candidate compound activates the receptor of claim 1,
wherein a compound that activates the receptor of claim 1 is an agonist of said receptor.

3. An isolated and purified receptor agonist identified by the method of claim 2.

4. (EPO) Use of a receptor agonist for the manufacture of a medicament for inhibiting

obesity, wherein said receptor agonist is identified by the method of claim 2.
(USPTO) A method for the treatment of obesity, comprising administering to a host in need thereof a therapeutically effective amount of the agonist identified by the method of claim 2.
(JPO) Composition comprising a receptor agonist for use in treating obesity, wherein said receptor agonist is identified by the method of claim 2, as an active ingredient.

5. A monoclonal antibody which recognizes the receptor of claim 1.

Case 3

Outline of Specification:

The application describes the isolation of a protein (SEQ ID NO: 3) which meets the novelty and inventive step (non-obviousness) requirements. Based upon the disclosed homology to known R-receptor amino acid sequences, there is no reason to doubt that the claimed receptor represents a new member of this protein family. The application describes methods of screening for compounds that activate this receptor. The application further discloses that different R-receptors are important in a wide variety of physiological processes, but does not disclose any particular biological or biochemical process in which this receptor is involved, except that its activation induces a cascade of second-messenger signals, similar to that of a G-protein coupled receptor.

The patent application specification includes a specific description of a series of screening procedures commensurate in scope with those recited in the claims. In particular, there is a description of a method of identifying or screening for agonists of this receptor, i.e., compounds that activate the claimed receptor, wherein the activated state is detected when a cascade of second-messenger signals occurs. There is no doubt that the skilled artisan could use the claimed R-receptor to identify (find) agonists.

In addition, the application discloses three working examples wherein compounds activating this receptor, namely X, Y, and Z were identified using the disclosed screening procedure.

The application provides no structural information for compounds other than X, Y, or Z or methods of making compounds other than X, Y, or Z.

Furthermore, although the receptor of SEQ ID NO: 3 was expressed in an animal cell, antibodies that recognize the receptor were not actually produced.

Claims:

1. An isolated and purified receptor the sequence of which consists of SEQ ID NO: 3.

2. A method of identifying an agonist of the receptor of claim 1 comprising:
preparing a candidate compound,
contacting a cell which expresses said receptor on its surface with said candidate compound, and

determining whether said candidate compound activates the receptor of claim 1, wherein a compound that activates the receptor of claim 1 is an agonist of said receptor.

3. An isolated and purified receptor agonist identified by the method of claim 2.

4. (EPO) Use of a receptor agonist for the manufacture of a medicament for treating a disease treatable by said agonist, wherein said receptor agonist is identified by the method of claim 2.
(USPTO) A method for the treatment of disease treatable by the agonist of claim 2, comprising administering to a host in need thereof a therapeutically effective amount of the agonist of claim 3.
(JPO) Composition comprising a receptor agonist for use in treating a disease treatable by said agonist, wherein said receptor agonist is identified by the method of claim 2, as an active ingredient.

5. (EPO) Use of compound X for the manufacture of a medicament for treating a disease treatable by said compound.
(USPTO) A method for treating a disease treatable by compound X comprising administering to a host in need thereof a therapeutically effective amount of compound X.
(JPO) Composition comprising compound X for use in treating a disease treatable by said compound, as an active ingredient.

6. A monoclonal antibody which recognizes the receptor of claim 1.

Case 4:

Outline of Specification:

The application describes the isolation of a receptor (SEQ ID NO: 4) which meets the novelty and inventive step (non-obviousness) requirements as well as methods of screening for compounds that activate this receptor. The application further discloses that the receptor is useful for the treatment of obesity.

The patent application specification includes a specific description of a series of screening procedures commensurate in scope with those recited in the claims.

In addition, the application discloses three working examples wherein agonists of this receptor, i.e., compounds activating this receptor, namely X, Y, and Z were identified using the disclosed screening procedure.

Furthermore, the pharmacological mechanism involved in the treatment or inhibition of obesity by the activation of this receptor is described theoretically in the specification.

In addition, *in vivo* test data confirms that at least compound X is able to activate this receptor when administered to a host animal and such administration results in a reduction in total body weight of an art recognized model for obesity.

The application provides no structural information for compounds other than X, Y, or Z

or methods of making compounds other than X, Y, or Z.

Furthermore, although the receptor of SEQ ID NO: 4 was expressed in an animal cell, antibodies that recognize the receptor were not actually produced.

Claims:

1. An isolated and purified receptor the sequence of which consists of SEQ ID NO: 4.

2. A method of identifying an agonist of the receptor of claim 1 comprising:
   preparing a candidate compound,
   contacting a cell which expresses said receptor on its surface with said candidate compound, and
   determining whether said candidate compound activates the receptor of claim 1,
   wherein a compound that activates the receptor of claim 1 is an agonist of said receptor.

3. An isolated and purified receptor agonist identified by the method of claim 2.

4. (EPO) Use of a receptor agonist for the manufacture of a medicament for inhibiting obesity, wherein said receptor agonist is identified by the method of claim 2.
   (USPTO) A method for the treatment of obesity comprising administering to a host in need thereof a therapeutically effective amount of the agonist identified by the method of claim 2.
   (JPO) Composition comprising a receptor agonist for use in treating obesity wherein said receptor agonist is identified by the method of claim 2, as an active ingredient.

5. (EPO) Use of compound X for the manufacture of a medicament for inhibiting obesity.
   (USPTO) A method for the treatment of obesity comprising administering to a host in need thereof a therapeutically effective amount of compound X.
   (JPO) Composition comprising compound X for use in treating obesity, as an active ingredient.

6. A monoclonal antibody which recognizes the receptor of claim 1.

C) Summary of the Cases

	Case 1	Case 2	Case 3	Case 4
Method used to support asserted function of receptor	homology search methods	experimental methods	homology search methods	experimental methods
Knowledge of the relationship between receptor and a specific disease (biological function)	unknown	confirmed	unknown	confirmed
Working example of claimed screening method	none	none	described	described
Receptor protein	claim 1	claim 1	claim 1	claim 1

Screening method	claim 2	claim 2	claim 2	claim 2
Receptor agonist (activating compound)	claim 3	claim 3	claim 3	claim 3
Medical application of receptor agonists (activating compounds) in general :Pharmaceutical compositions, methods for treatment, or uses for the manufacture of a medicament	claim 4	claim 4	claim 4	claim 4
Medical application of defined receptor agonists (activating compounds) :Pharmaceutical compositions, methods for treatment, or uses for the manufacture of a medicament			claim 5	claim 5
Monoclonal antibody which recognizes receptor	claim 5	claim 5	claim 6	claim 6

4. Summary of Answers

A) Receptor Proteins (Claim 1 of Cases 1 - 4)

Industrial Applicability (Application) / Utility

The three Offices concluded that there was no industrial applicability (application)/utility for claim 1 in Cases 1 and 3. The amino acid sequences of the Cases are not assigned to a particular (specific) function, i.e., there is no indication of a specific and substantial use for the protein, and therefore the claim does not comply with industrial applicability (application)/utility.

For Cases 2 and 4, the receptor is useful in diagnostic methods relating to obesity, and therefore, complies with industrial applicability (application) and utility.

Enablement / Support / Clarity and/or Written Description

The three Offices concluded that for all Cases, the claim is clear, since the receptor is defined by an amino acid sequence, and since the sequence is specifically disclosed.
The three Offices concluded that in all the Cases, the person skilled in the art (skilled artisan) can understand "how to make" (prepare) the protein.
However, in Cases 1 and 3, since the specific function of the receptor has not been disclosed, it would require undue experimentation (or be an undue burden) for the person skilled in the art, to understand "how to use" the receptor (or perform the invention over its entire scope), and thus, claim 1 in these Cases lack enablement.

The three offices concluded that in Cases 2 and 4, the claim meets the requirement of enablement, support, clarity, and/or written description.

Other Comments

(EPO) Case 1: No obvious possibility to overcome all the objections above. (Amendments are likely to violate Art. 123 (2) EPC.)

Case 3: No obvious possibility to overcome objection, unless in the context of compounds X, Y, Z there is a more concrete indication of function.

Cases 1 and 3: Objections are also made on the basis of lack of inventive step. Prima facie, the routine provision of further sequences having the same general function as the known prior art sequences of closely related structure is not inventive. The structural non-obviousness is not a reason to accept an inventive step; sequences as well as all chemical compounds should solve a technical problem in a non-obvious manner to be recognized as inventive. (As a consequence, inventive step of claims 2 and 6 of Cases 1 and 3 are also denied.)

(USPTO) Cases 1 and 3: Objective evidence might overcome rejection for utility if it supports an assertion that one of ordinary skill in the art would recognize that each member of the R-receptor protein family would have been reasonably expected to have a particular specific and substantial function or activity.

(JPO) Case 1 and 3: No obvious possibility to overcome reason for refusal, at least for lack of enablement.

B) Screening Methods (Claim 2 of Cases 1 - 4)

Industrial Applicability (Application) / Utility

The three Offices concluded that claim 2 does not meet industrial applicability (application)/utility in Cases 1 and 3, since there can be no industrial applicability (application)/utility for methods of identifying agonists that are asserted to stimulate an unknown function.

However, claim 2 does meet the requirements in Cases 2 and 4, since the claimed methods for identifying agonists are industrially applicable/useful in view of the proven pharmaceutical relevance of the receptor.

Enablement / Support / Clarity and/or Written Description

For Cases 1 and 3, the three Offices concluded that the claim does not comply with enablement, support, clarity, and/or written description.

For Cases 1 and 3, the Trilateral Offices concluded that since the specification does not provide any guidance with respect to the activity of the receptor, nor any working examples, the person skilled in the art cannot use the claimed assay without undue experimentation. Since the description does not describe how the "agonist compound" can be used, the claim lacks enablement. For Case 3, however, the EPO stated that the

be used, the claim lacks enablement. For Case 3, however, the EPO stated that the objection should preferably be made under "lack of inventive step."

For Case 1, the Trilateral Offices concluded that the claim does not comply with written description (USPTO), or is not sufficiently supported by the description (EPO), or is unclear (JPO), since the method of analyzing any activity of the receptors is unclear to the person skilled in the art.

However, for Case 3, the three Offices concluded that the requirement for an adequate written description (USPTO), or clarity and support (EPO), or clarity of claims (JPO) is met because the specification teaches methods of screening for compounds that activate this receptor and thus one skilled in the art would conclude that the applicant was in possession of such methods. Furthermore, the “how to make” prong of the enablement requirement of 35 U.S.C. § 112, first paragraph is met since the specification specifically teaches methods of screening for compounds that activate the claimed receptor of claim 1.

For Cases 2 and 4, the three Offices concluded that the claim complies with enablement, support, clarity, and/or written description.
The specification in Case 4 discloses methods of screening for compounds that activate this receptor as well as working examples, and the receptor’s activity is disclosed. The description also teaches the relationship of the receptor with a specific disease, i.e. obesity. Therefore, the requirements of enablement, support, clarity, and/or written description are met.
In Case 2, the description provides general reference toward standard screening methods. Although the description does not provide working examples, the description teaches a method for measuring the biochemical and binding activity of the specific receptor, and the person skilled in the art can understand how to use the screening method considering the common general knowledge. Therefore, the requirements of enablement, support, clarity, and/or written description are met as well.

Other Comments

(EPO) Cases 1 and 3: No obvious possibility to overcome all the rejections above. (Amendments are likely to violate Art.123 (2) EPC.)

(USPTO) Cases 1 and 3:Objective evidence might overcome rejection for utility if it supports an assertion that one of ordinary skill in the art would recognize a specific, substantial, and credible utility for the agonist, or "how to use" the agonist, identified by the claimed method.

(JPO) Cases 1 and 3: No obvious possibility to overcome reason for refusal, at least for lack of enablement.

C) Agonists (Activating Compounds) Identified by the Screening Method Of Claim 2, and Medical Application of Agonists (Activating Compounds) of Claim 3 (Claim 3 & 4 of Cases 1 - 4)

Industrial Applicability (Application) / Utility

The three Offices concluded that in Cases 1 and 3, industrial applicability (application)/ utility is not met for the same reason as discussed for claims 1 and 2.

The three Offices also concluded that for Case 4, industrial applicability (application)/ utility is met for the same reason as discussed for claims 1 and 2.

As for Case 2, the JPO and USPTO concluded that the claim complies with industrial applicability (application)/ utility, for the same reason as discussed for claims 1 and 2. The EPO concluded that although it can be said that a compound that has not been disclosed cannot be made and used in any kind of industry, it can also be argued that the person skilled in the art would know that there is a potential application for agonists in the treatment of obesity. The question "Industrial application, yes or no" has however no practical relevance in this case, since the Lack of Support is so striking.

Enablement / Support / Clarity and/or Written Description

The three Offices concluded that except for compounds X, Y and Z in Case 4, the general scope of claims 3 and 4 in Cases 1-4 do not comply with enablement, support and/or written description requirements. The claims encompass a genus of compounds defined only by their function wherein the relationship between the structural features of the members of the genus and said function have not been defined. In the absence of such a relationship either disclosed in the as-filed application or which would have been recognized based upon information readily available to one skilled in the art, the skilled artisan would not know how to make and use compounds that lack structural definition. The fact that one could have assayed a compound of interest using the claimed assays does not overcome this defect since one would have no knowledge beforehand as to whether or not any given compound (other than those that might be particularly disclosed in an application) would fall within the scope of what is claimed. It would require undue experimentation (be an undue burden) to randomly screen undefined compounds for the claimed activity.

In Cases 1 and 3, where the specific function (e.g., its relationship to a specific disease) of a receptor is not disclosed, claim 4 referring to a "disease treatable by the agonist" of the said receptor is unclear.

Other Comments

(EPO) All Cases: The claim will be objected at the search stage, and no search will be

carried out for compounds which are only defined by the method for their identification.

Cases 1, 2, and 3: No obvious possibility to overcome the rejections above.

Cases 4: Possibilities to overcome the rejections above: restriction to X,Y,Z.

(USPTO) Case 1 and 3 (Claim 4-Utility): Objective evidence might overcome rejection of utility, if it supports an assertion that one of the ordinary skill in the art would have known what disease(s) would have been treatable with the undisclosed agonist.

Case 3 (Claim 3-Utility): The rejection for lack of utility in claim 3 might be overcome with a showing of objective evidence that supports the position that one of ordinary skill in the art would recognize that each member of the R-receptor protein family would have been reasonably expected to have a particular specific and substantial function or activity, or that a specific and substantial purpose for agonizing such function would have been known to those of skill in the art.

Cases 3 and 4 (Claim 3-Written description): The written description rejection might be overcome by showing of objective evidence that supports the proposition that the particularly disclosed receptor agonists were representative of the structure of the group of molecules that would be detected or identified by the claimed method. The written description rejection may also be overcome by limiting the scope of the claim in each Case to the specifically disclosed agonists (X, Y, and Z).

Case 4 (Claims 3 and 4 – Written description and enablement): The written description and enablement rejections may be overcome by limiting the scope of the claimed agonists to X, Y, and Z.

(JPO) Cases 1, 2 and 3: No obvious possibility to overcome reason for refusal, at least for lack of enablement.

Case 4: A restriction of the agonists (activating compounds) to the compounds which can be made by the person skilled in the art according to the description and considering the common general knowledge at the time of filing, would overcome the reason for refusal concerning lack of enablement. However, amendments must be made within the scope of the original specification (Patent Law Sec.17 bis).

Restriction to compounds X,Y,Z, which can be made by the person skilled in the art according to the description and considering the common general knowledge, will overcome the reasons for rejection above in Case 4.

D) Medical Application of Specific Compounds Identified by the Screening Methods: Pharmaceutical Compositions, Methods for Treatment, or Use for the Manufacture of Medicaments (Claim 5 of Cases 3 & 4)

Industrial Applicability (Application) / Utility

In Case 3, the three Offices concluded that unless a specific disease is known, the claim relating to the treatment of the disease do not fulfil the requirements of industrial applicability (application) / utility.

In Case 4, the three Offices concluded that since the claim is drawn to the treatment of a particular disease, the claim complies with industrial applicability (application) / utility.

Enablement / Support / Clarity and/or Written Description

In Case 3, the Trilateral Offices concluded that unless a specific disease is known, the claim relating to the treatment of the disease is unlikely to fulfil the requirements of enablement, support, clarity, and/or written description.

In Case 4, the claim fulfils the requirements of enablement, support, clarity, and/or written description, since the claimed invention is drawn to treating is a specific disease using specific and disclosed compounds, the person skilled in the art can understand how to make and use the invention, and there is no reason to doubt the effect of the compound.

E) Monoclonal Antibodies Which Recognize the Claimed Receptor (Claim 5 of Cases 1 & 2, Claim 6 of Cases 3 & 4)

Industrial Applicability (Application) / Utility

The three Offices concluded that for Cases 1 and 3, claim 5(or 6) does not comply with industrial applicability and utility requirements, but for Cases 2 and 4, the claim does comply with the said requirements, for the reasons stated for claim 1.

Enablement / Support / Clarity and/or Written Description

The three Offices concluded that the claim complies with clarity, and/or written description, for Cases 1-4. Monoclonal antibodies are traditionally defined by their target (i.e., its antigen), so the claim is usually clear to the person skilled in the art, and in view of the manner in which antibodies are made, it is also generally accepted that if one is in possession of any particular protein sequence, one would also have been “in possession” of its antibody.

The claim complies with enablement and/or support requirements in Case 2 and 4, since the person skilled in the art could obtain a monoclonal antibody specific to a given protein, using routine and well known methods, and use the antibodies in diagnostic methods.

The three Offices concluded that for Cases 1 and 3, the claim does not comply with enablement / support, since although the person skilled in the art can make the antibody

using routine procedures, it would require undue experimentation (or be an undue burden) for the person skilled in the art to determine the specific function of the antibody and thus determine how to use the antibody.

Other Comments

See the comments in "A) Receptor Proteins (Claim 1 of Cases 1 - 4)."

(EPO) In cases where the receptor families are of closely related structure, it may become necessary to restrict the scope of the present claims to specific antibodies, in order to distinguish these antibodies from potentially existing prior art antibodies against the related receptors and thereby overcoming a possible novelty objection. However, attention must be paid that in the present Cases, there seems to be no basis in the description as filed for such an amendment.

F) Summary of Answers

(In the following answers, Y stands for 'Yes', N stands for 'No')

USPTO

Case	Claim	Utility	Written Description	Enablement	
				"How to Make"	"How to Use"
1	1	N	Y	Y	N
	2	N	N	N	N
	3	N	N	N	N
	4	N	N	N	N
	5	N	Y	Y	N
2	1	Y	Y	Y	Y
	2	Y	Y	Y	Y
	3	Y	N	N	N
	4	Y	N	N	N
	5	Y	Y	Y	Y
3	1	N	Y	Y	N
	2	N	Y	Y	N
	3	N	N/Y (scope)	N/Y (scope)	N
	4	N	N	N	N
	5	N	N	N	N
	6	N	Y	Y	N
4	1	Y	Y	Y	Y
	2	Y	Y	Y	Y
	3	Y	N/Y (scope)	N/Y (scope)	N/Y (scope)
	4	Y	N/Y (scope)	N/Y (scope)	N/Y (scope)
	5	Y	Y	Y	Y
	6	Y	Y	Y	Y

EPO

Case	Claim	Industrial Applicability	Clarity/Support	Sufficiency
1	1	N	Y	Y/N*
	2	N	Y/N	N
	3	N	N	N
	4	N	N	N
	5	N	Y	Y/N*
2	1	Y	Y	Y
	2	Y	Y	Y
	3	Y	N	N
	4	Y	N	N
	5	Y	Y	Y
3	1	N	Y	Y/N*
	2	N	Y	Y/N*
	3	N	N	N
	4	N	N	N
	5	N	N	N
	6	N	Y	Y/N*
4	1	Y	Y	Y
	2	Y	Y	Y
	3	Y	Y/N (scope)	Y/N (scope)
	4	Y	Y/N (scope)	Y/N (scope)
	5	Y	Y	Y
	6	Y	Y	Y

*debatable whether it would be an undue burden to perform the invention over the whole area, since the specific function of receptor has not been disclosed; it is, however, a problem that should be dealt with under "lack of inventive step."

JPO

Case	Claim	Industrial Applicability	Clarity	Enablement
1	1	N	Y	N
	2	N	N	N
	3	N	N	N
	4	N	N	N
	5	N	Y	N
2	1	Y	Y	Y
	2	Y	Y	Y
	3	Y	N	N
	4	Y	N	N
	5	Y	Y	Y
3	1	N	Y	N
	2	N	Y	N
	3	N	N	N
	4	N	N	N
	5	N	N	N
	6	N	Y	N
4	1	Y	Y	Y
	2	Y	Y	Y

	3	Y	N	N*
	4	Y	N	N*
	5	Y	Y	Y
	6	Y	Y	Y

* to the general scope of the claim

5. Conclusion

Summary of Comments: Fulfillment of Requirements of Industrial Applicability, Utility, Enablement, Support, Clarity and/or Written Description

(For the following chart, 'Y' means all the above requirements are met, whereas 'N' means more than one of the requirements are not met, considering the general scope of the claims.)

Case	Claim	USPTO	EPO	JPO
1	1	**N**	**N**	**N**
	2	**N**	**N**	**N**
	3	**N**	**N**	**N**
	4	**N**	**N**	**N**
	5	**N**	**N**	**N**
2	1	**Y**	**Y**	**Y**
	2	**Y**	**Y**	**Y**
	3	**N**	**N**	**N**
	4	**N**	**N**	**N**
	5	**Y**	**Y**	**Y**
3	1	**N**	**N**	**N**
	2	**N**	**N**	**N**
	3	**N**	**N**	**N**
	4	**N**	**N**	**N**
	5	**N**	**N**	**N**
	6	**N**	**N**	**N**
4	1	**Y**	**Y**	**Y**
	2	**Y**	**Y**	**Y**
	3	**N**	**N**	**N**
	4	**N**	**N**	**N**
	5	**Y**	**Y**	**Y**
	6	**Y**	**Y**	**Y**

The three Offices shared the following views:

1. In cases where the specific function (e.g., the relationship to a specific disease) of a receptor protein is not disclosed, the claims for:
   (1) the receptor
   (2) screening methods using said receptor

(3) agonists (activating compounds) in general identified by said screening methods
(4) methods, uses, or medicaments utilizing said agonists (activating compounds) in general
(5) methods, uses, or medicaments utilizing the specific agonists (activating compounds) and
(6) monoclonal antibodies which recognize the receptor

do not comply with one or more of the requirements of industrial applicability (application), utility, enablement, support, clarity, and/or written description

2. In cases where the specific function (e.g., the relationship to a specific disease) of a receptor is disclosed, claims for:
(1) the receptor
meet all the requirements of industrial applicability (application), utility, enablement, support, clarity and written description.
In such case, claims for:
(2) screening methods using said receptor
meet all the requirements of industrial applicability (application), utility, enablement, support, clarity and written description if:
(a) there is a working example of the screening method, or
(b) there is a general reference to standard screening methods that can be applied with a reasonable expectation of success, together with the disclosure of a method for measuring the biochemical and binding activity of the specific receptor, or
(c) the person skilled in the art can understand how to use the screening method, considering the common general knowledge.

3. Regardless of whether the specific function (e.g., the relationship to a specific disease) of a receptor protein is disclosed, the claims for:
(3) agonists (activating compounds) in general identified by said screening methods and
(4) methods, uses, or medicaments utilizing said agonists (activating compounds) in general
do not meet enablement and/or support requirements, considering the general scope of the claims. The claims encompass a genus of compounds defined only by their function wherein the relationship between the structural features of the members of the genus and said function have not been defined. In the absence of such a relationship either disclosed in the as-filed application or which would have been recognized based upon information readily available to one skilled in the art, the skilled artisan would not know how to make and use compounds that lack structural definition. The fact that one could have assayed a compound of interest using the claimed assays does not overcome this defect since one would have no knowledge beforehand as to whether or not any given compound (other than those that might be particularly disclosed in an application) would

fall within the scope of what is claimed. It would require undue experimentation (be an undue burden) to randomly screen undefined compounds for the claimed activity.

4. In cases where the specific function (e.g., the relationship to a specific disease) of a receptor protein is disclosed, and specific agonists (activating compounds) are identified (found) by screening methods using said receptor, the claims for:

   (5) methods, uses, or medicaments utilizing the specific agonists (activating compounds)

   meet all the requirements of industrial applicability (application), utility, enablement, support, clarity and written description as long as there is adequate guidance with respect to how such uses would be put into effect. Furthermore, claims limited to the specific agonists identified (found) by the screening method using the receptor would meet all the requirements of industrial applicability (application), utility, enablement, support, clarity and written description if the agonists could be made by the person skilled in the art in view of the description in the specification and the common general knowledge in the art.

5. In cases where the specific function (e.g., the relationship to a specific disease) of a receptor protein is disclosed, the claims for:

   (6) monoclonal antibodies which recognize the receptor

   meet all the requirements of industrial applicability (application), utility, enablement, support, clarity and written description if the receptor is clearly described.

ANNEX 1: Comments of the USPTO

Questionnaire for Comparative Study on "Reach-Through Claims"

Questions:

1. Do the following claims satisfy clarity, enablement, support and written description requirements? If not, explain why.
2. Do the following claims satisfy the industrial applicability or utility requirements? If not, explain why.
3. If there are any comments on the kind of evidence, argument, and/or claim amendment that may overcome any rejection for failure to satisfy the requirement of 1 and/or 2 above, please state them.

Fact Pattern	Claim	Utility	Written Description	Enablement	
				"How to Make"	"How to Use"
1	1	N	Y	Y	N
	2	N	N	N	N
	3	N	N	N	N
	4	N	N	N	N
	5	N	Y	Y	N
2	1	Y	Y	Y	Y
	2	Y	Y	Y	Y
	3	Y	N	N	N
	4	Y	N	N	N
	5	Y	Y	Y	Y
3	1	N	Y	Y	N
	2	N	Y	Y	N
	3	N	N /Y(scope)	N/Y (scope)	N
	4	N	N	N	N
	5	N	N	N	N
	6	N	Y	Y	N
4	1	Y	Y	Y	Y
	2	Y	Y	Y	Y
	3	Y	N/Y (scope)	N/Y (scope)	N/Y (scope)
	4	Y	N/Y (scope)	N/Y (scope)	N/Y (scope)
	5	Y	Y	Y	Y
	6	Y	Y	Y	Y

Example **1:**

Outline of the Specification:

The application describes the isolation of a protein (SEQ ID NO:1) which meets the novelty and inventive step (non-obviousness) requirements. Based upon the disclosed homology to known R-receptor amino acid sequences, there is no reason to doubt that the claimed receptor represents a new member of this protein family. The application further discloses that different R-receptors are important in a wide variety of physiological processes, but does not disclose any ligand for the receptor of SEQ ID NO: 1 or any particular biological or biochemical process in which this receptor is involved.

The patent application specification includes a general description of a series of screening procedures commensurate in scope with those recited in the claim. However, the application discloses no working examples wherein agonists of this receptor, i.e., compounds activating this receptor, are identified using the disclosed screening procedure.

Furthermore, although the receptor of SEQ ID NO: 1 was expressed in an animal cell, antibodies that recognize the receptor were not actually produced.

Claims:

1. An isolated and purified receptor the sequence of which consists of SEQ ID NO: 1.

35 U.S.C. § 101: Utility

To comply with 35 U.S.C. § 101, the claimed invention must have at least one specific, substantial, and credible utility that is either asserted in the specification or well-established.

In this example, the fact pattern indicates that there is no reason to doubt that the claimed protein is a member of the R-receptor family of proteins and that different R-receptors are important to a wide variety of physiological processes. Assignment to a prior art family of proteins is generally insufficient to meet the utility requirement unless such assignment would allow the artisan to assign a specific and substantial use to the new member of the protein family. Because there is no indication of a specific and substantial use for the claimed member of the R-receptor family of proteins, this claim does not comply with the utility requirement of 35 U.S.C. § 101.

Objective evidence might overcome this rejection if it supports an assertion that one of ordinary skill in the art would recognize that each member of the R-receptor protein family would have been reasonably expected to have a particular specific and substantial function or activity.

35 U.S.C. § 112, first paragraph: Written Description

To comply with the written description requirement of 35 U.S.C. § 112, first paragraph, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. An applicant shows

possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention. Possession may be shown in a variety of ways including description of an actual reduction to practice, or by showing that the invention was "ready for patenting" such as by the disclosure of drawings or structural chemical formulas that show that the invention was complete, or by describing distinguishing identifying characteristics sufficient to show that the applicant was in possession of the claimed invention.

This claim meets the requirement for an adequate written description of the claimed invention because the scope of the claim is limited to a protein molecule whose primary structure is specifically disclosed.

35 U.S.C. § 112, first paragraph: Enablement

To comply with the enablement requirement of 35 U.S.C. § 112, first paragraph, the specification must enable one skilled in the art to make and use the claimed invention without undue experimentation. Factors to be considered in determining whether any necessary experimentation is "undue" include the breadth of the claims, the nature of the invention, the state of the prior art, the level of ordinary skill in the art, the level of predictability in the art, the amount of direction provided by the inventor, the presence or absence of working examples, and the quantity of experimentation needed to make or use the invention based on the content of the disclosure.

This claim meets the enablement requirement for the "how to make" prong of 35 U.S.C. § 112, first paragraph because given the primary protein sequence, the skilled artisan would have been able to prepare the claimed protein. However, this claim does <u>not</u> meet the requirement for the "how to use" prong of 35 U.S.C. § 112, first paragraph because there is no disclosed use that would meet the utility requirement of 35 U.S.C. § 101 (see utility discussion, above).

2. A method of identifying an agonist of the receptor of claim 1 comprising:
   preparing a candidate compound,
   contacting a cell which expresses said receptor on its surface with said candidate compound, and
   determining whether said candidate compound activates the receptor of claim 1,
   wherein a compound that activates the receptor of claim 1 is an agonist of said receptor.

35 U.S.C. § 101: Utility

This claim does not comply with the utility requirement for the reasons noted with respect to claim 1. There is no specific, substantial, and credible utility for the receptor of claim 1. Furthermore, the specification does not assert any specific, substantial, and credible utility for an agonist (activating compound) of the receptor of claim 1. Therefore the claimed method of identifying an agonist (activating compound) of the receptor of claim 1 does not comply with the utility requirement.

tivating compound) of the receptor of claim 1 does not comply with the utility requirement.

Objective evidence might overcome this rejection if it supports an assertion that one of ordinary skill in the art would recognize a specific, substantial, and credible utility for the agonist identified by the claimed method. A method of detecting a useful product has utility; a method of detecting a product that has no known utility is not useful.

35 U.S.C. § 112, first paragraph: Written Description

The claim is directed to a method of identifying an agonist that activates the receptor of claim 1. While the specification does provide an adequate written description of the receptor of claim 1 (as noted above), there is no disclosure of the activity of the receptor, nor any method for analyzing any such activity. There is no description of the identifying characteristics for recognizing that a candidate compound activates the receptor. There is no description of an actual reduction to practice, each step of the claimed method, or distinguishing identifying characteristics sufficient to show that the applicant was in possession of the claimed invention. Therefore, the claim fails to comply with the written description requirement.

35 U.S.C. § 112, first paragraph: Enablement

The claim is directed to a method of identifying an agonist that activates the receptor of claim 1. The specification does not provide any guidance with respect to the activity of the receptor, nor any working examples. One skilled in the art would first have to determine the activity of the receptor in order to develop the claimed assay. The claim does not comply with the enablement requirement because the skilled artisan would not have been able to make the claimed assay without undue experimentation.

Similarly, and for reasons set forth above in the analysis of the compliance of the claimed invention with the requirements of 35 U.S.C. § 101, the claimed methods fails to meet the requirements of "how to use" prong of 35 U.S.C. § 112, first paragraph. See the discussion of the utility requirement for objective evidence that might overcome this rejection.

3. An isolated and purified receptor agonist identified by the method of claim 2

35 U.S.C. § 101: Utility

This claim fails to comply with the utility requirement for the reasons set forth with respect to claims 1 and 2.

35 U.S.C. § 112, first paragraph: Written Description

The claimed invention is drawn to an agonist identified by the method of claim 2. However, no structural or specific functional characteristics of such an agonist are provided, nor is there any indication that the applicant had possession of any agonist. This situation is analogous to that of *Regents of the University of California v. Eli Lilly*, 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997). Because one skilled in the art would conclude that the inventors were not in possession of the claimed invention, the claim fails to comply with the written description requirement.

35 U.S.C. § 112, first paragraph: Enablement

The specification fails to disclose any particular structure for the claimed agonist. The specification does not provide any guidance or any working examples in this unpredictable art, and thus the artisan would have been unable to prepare the claimed agonist. Furthermore, an assay for *finding* a product is not equivalent to a positive recitation of *how to make* a product. This claim fails to meet the enablement requirement for the "how to make" prong of 35 U.S.C. § 112, first paragraph.

Similarly, and for reasons set forth above in the analysis of the compliance of the claimed invention with the requirements of 35 U.S.C. § 101, the claimed agonist fails to meet the requirements of the "how to use" prong of 35 U.S.C. § 112, first paragraph.

4. (EPO) Use of a receptor agonist for the manufacture of a medicament for treating a disease treatable by said agonist, wherein said receptor agonist is identified by the method of claim 2.
   (USPTO) A method for the treatment of disease treatable by the agonist of claim 2, comprising administering to a host in need thereof a therapeutically effective amount of the agonist identified by the method of claim 2.
   (JPO) Composition comprising a receptor agonist for use in treating a disease treatable by said agonist, wherein said receptor agonist is identified by the method of claim 2, as an active ingredient.

35 U.S.C. § 101: Utility

This claim does not comply with the utility requirement of 35 U.S.C. § 101 for the reasons set forth with respect to claims 1 and 2, above. Furthermore, the instantly claimed invention is drawn to a method of treating an undisclosed disease. Since the fact pattern fails to establish what disease, if any, would be treatable by the undisclosed agonist, the claimed treatment does not encompass a specific, substantial, and credible utility.

Objective evidence might overcome this rejection if it supports an assertion that one of ordinary skill in the art would have known what disease(s) would have been treatable with the undisclosed agonist.

35 U.S.C. § 112, first paragraph: Written Description

This claim does not comply with the written description requirement for the reasons set forth with respect to claims 2 and 3. Further, the claimed method requires treatment of an unspecified disease. One skilled in the art would conclude that the artisan was not in possession of the claimed method of use.

35 U.S.C. § 112, first paragraph: Enablement

This claim does not comply with the "how to make" prong of the enablement requirement for the reasons set forth with respect to claims 2 and 3. Furthermore, no information is presented as to how the undisclosed agonist would have been administered to treat an unspecified disease. Thus, the skilled artisan would not have been able to practice the steps required by the claimed invention.

Similarly, and for reasons set forth above in the analysis of the compliance of the claimed invention with the requirements of 35 U.S.C. § 101, the claimed method fails to meet the requirements of "how to use" prong of 35 U.S.C. § 112, first paragraph.

Objective evidence might overcome this rejection if it shows by a preponderance of the evidence that, at the time of filing, the activity and use of the claimed R-receptor of claim 1 as well as its association with some disease state was known. Further, to show utility of the claimed method, objective evidence should provide some indication that increasing or enhancing the activity of the R-receptor would result in treatment of the unspecified disease.

5. A monoclonal antibody which recognizes the receptor of claim 1.

35 U.S.C. § 101: Utility

This claim would not meet the utility requirement of 35 U.S.C. § 101 for the reasons set forth with respect to claim 1. Given that there is no specific, substantial, and credible utility for claimed receptor, there would be no specific and substantial practical benefit or utility for detecting the receptor with the claimed antibody or to use the antibody in any other manner.

Objective evidence might overcome this rejection if it supports an assertion that one of ordinary skill in the art would recognize that each member of the R-receptor protein family would have been reasonably expected to have a particular specific and substantial function or activity.

35 U.S.C. § 112, first paragraph: Written Description

This claim meets the requirement for an adequate written description of the claimed invention as required by 35 U.S.C. § 112, first paragraph. The scope of the claim is limited to an antibody that

binds to a particularly recited protein. In view of the manner in which antibodies are made, it is generally accepted that if one is in possession of any particular protein sequence, one would also have been "in possession" of its antibody.

35 U.S.C. § 112, first paragraph: Enablement

This claim meets the enablement requirement for the "how to make" prong of 35 U.S.C. § 112, first paragraph. Given the primary protein structure to which an antibody is to be made, one skilled in the art would have been able to use routine and well known methods to prepare an antibody to such a target.

However, this claim does not meet the requirement for the "how to use" prong of 35 U.S.C. § 112, first paragraph, since there is no disclosed use that would meet the utility requirement of 35 U.S.C. § 101.

Example 2

Outline of Specification:

The application describes the isolation of a receptor (SEQ ID NO: 2) which meets the novelty and inventive step (non-obviousness) requirements as well as methods of screening for compounds that activate this receptor. The application further discloses that the receptor is useful for the treatment of obesity.

The relationship between the absence of this receptor and the occurrence of obesity is determined by experimental measures, and there is no doubt that the activation of this receptor can treat or inhibit obesity.

The patent application specification includes a general description of a series of screening procedures commensurate in scope with those recited in the claims. The description also teaches a method of measuring the biochemical and binding activity of this specific receptor, and there is no doubt that these activities can be measured. However, the application discloses no working examples wherein agonists of this receptor, i.e., compounds activating this receptor, are identified using the disclosed screening procedure. Furthermore, although the receptor of SEQ ID NO: 2 was expressed in an animal cell, antibodies that recognize the receptor were not actually produced.

Claims:

1. An isolated and purified receptor the sequence of which consists of SEQ ID NO: 2.

35 U.S.C. § 101: Utility

See Example 1, claim 1 for a discussion of the relevant patentability considerations.

This claim meets the utility requirement of 35 U.S.C. § 101. Only one specific, substantial, and

credible utility is required to support the requirements of 35 U.S.C. § 101. In the instant case, the presence or absence of the receptor is useful in diagnostic methods relating to obesity.

35 U.S.C. § 112, first paragraph: Written Description

See Example 1, claim 1 for a discussion of the relevant patentability considerations.

This claim meets the requirement for an adequate written description of the claimed invention as required by 35 U.S.C. § 112, first paragraph. The scope of the claim is limited to a protein molecule whose primary structure is specifically disclosed.

35 U.S.C. § 112, first paragraph: Enablement

See Example 1, claim 1 for a discussion of the relevant patentability considerations.

This claim meets the enablement requirement for the "how to make" prong of 35 U.S.C. § 112, first paragraph. Given the primary protein sequence, the skilled artisan would have been able to prepare the claimed protein. The claim meets the "how to use" prong of 35 U.S.C. § 112, first paragraph, since the receptor's presence or absence may be used in diagnostic methods relating to obesity.

2. A method of identifying an agonist of the receptor of claim 1 comprising:
   preparing a candidate compound,
   contacting a cell which expresses said receptor on its surface with said candidate compound, and
   determining whether said candidate compound activates the receptor of claim 1,
   wherein a compound that activates the receptor of claim 1 is an agonist of said receptor.

35 U.S.C. § 101: Utility

The treatment of obesity using agonist compounds identified by the claimed method is a specific, substantial, and credible utility, and therefore the claim complies with the utility requirement of 35 U.S.C. § 101.

35 U.S.C. § 112, first paragraph: Written Description

The claimed method of identifying agonist compounds meets the requirement for an adequate written description as required by 35 U.S.C. § 112, first paragraph, because the specification teaches methods of screening for compounds that activate this receptor and the receptor's activity is disclosed.

35 U.S.C. § 112, first paragraph: Enablement

This claim also meets the requirements for how to make and use the claimed method of identifying agonist compounds because the specification specifically teaches methods of screening for compounds that activate the claimed receptor of claim 1, and the receptor's activity is disclosed.

3. An isolated and purified receptor agonist identified by the method of claim 2.

35 U.S.C. § 101: Utility

The claimed receptor agonist meets the requirement for utility as set forth in 35 U.S.C. § 101 for reasons set forth above in the analysis of claims 1 and 2.

35 U.S.C. § 112, first paragraph: Written Description

The claimed invention is drawn to an agonist identified by the method of claim 2. However, no structural or specific functional characteristics of such an agonist is provided, nor is there any indication that the artisan actually implemented the method of claim 2 so as to identify any agonist. This situation is analogous to that of *Regents of the University of California v. Eli Lilly*, 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997). Because one skilled in the art would conclude that the inventors were not in possession of the claimed invention, the claim fails to comply with the written description requirement.

35 U.S.C. § 112, first paragraph: Enablement

The instant fact pattern fails to disclose any particular structure for the claimed agonist. The specification does not provide any guidance or any working examples in this unpredictable art, and thus the artisan would have been unable to have prepared the claimed agonist without undue experimentation. Furthermore, an assay for *finding* a product is not equivalent to a positive recitation of *how to make* such a product. This claim fails to meet the enablement requirement for the "how to make" prong of 35 U.S.C. § 112, first paragraph.

While the claimed agonist meets the utility requirement of 35 U.S.C. § 101, the claimed invention does not comply with the "how to use" prong of 35 U.S.C. § 112, first paragraph. The specification does not teach how to administer the claimed agonist compound so as to effect a viable obesity treatment regimen. Treatment/administration protocols depend upon the nature of the compound being administered as well as the clinical condition of the subject or patient. In the absence of additional information the skilled artisan would not have been able to use the undisclosed compound(s) for treatment without undue experimentation.

4. (EPO) Use of a receptor agonist for the manufacture of a medicament for inhibiting obesity, wherein said receptor agonist is identified by the method of claim 2.
(USPTO) A method for the treatment of obesity, comprising administering to a host in need thereof a therapeutically effective amount of the agonist identified by the method of claim 2.
(JPO) Composition comprising a receptor agonist for use in treating obesity, wherein said receptor agonist is identified by the method of claim 2, as an active ingredient.

35 U.S.C. § 101: Utility

This claim meets the utility requirement of 35 U.S.C. § 101 since the method is drawn to the treatment of a particular disease of real world relevance. In addition, based upon the instant fact pattern, there is no reason to question the assertion that one could potentially treat obesity with agonists to the claimed R-receptor.

35 U.S.C. § 112, first paragraph: Written Description

This claim fails to meet the requirement for an adequate written description of the claimed invention as required by 35 U.S.C. § 112, first paragraph for the reasons set forth with respect to claim 3. The claimed invention is drawn to a method of treatment that requires the use of an undisclosed agonist. In order to evidence possession of the claimed method, one would need to demonstrate possession of the claimed process steps which require the use of an undisclosed compound.

35 U.S.C. § 112, first paragraph: Enablement

This claim fails to meet the enablement requirement for the "how to make" prong of 35 U.S.C. § 112, first paragraph for the reasons set forth with respect to claim 3. Given that there is no disclosure of any particular agonist and how to administer it, one skilled in the art would not have been able to have practiced the process steps recited in the claim without undue experimentation.

The claim fails to meet the requirements for the "how to use" prong of 35 U.S.C. § 112 for the reasons set forth with respect to claim 3.

5. A monoclonal antibody which recognizes the receptor of claim 1.

35 U.S.C. § 101: Utility

This claim meets the utility requirement of 35 U.S.C. § 101. Only one specific, substantial, and credible utility is required to support the requirements of 35 U.S.C. § 101. In the instant case, assaying the presence or absence of the receptor is useful in diagnostic methods relating to obesity and an antibody could be used in such assays.

35 U.S.C. § 112, first paragraph: Written Description

This claim meets the requirement for an adequate written description of the claimed invention as required by 35 U.S.C. § 112, first paragraph. The scope of the claim is limited to an antibody that binds to a particularly recited protein. In view of the manner in which antibodies are made, it is generally accepted that if one is in possession of any particular protein sequence, one would also have been "in possession" of its antibody.

35 U.S.C. § 112, first paragraph: Enablement

This claim meets the enablement requirement for the "how to make" prong of 35 U.S.C. § 112, first paragraph. Given the primary protein structure to which an antibody is to be made, one would have been able to used routine and well known methods to prepare an antibody to such a target.

This claim meets the requirement for the "how to use" prong of 35 U.S.C. § 112, first paragraph, since there were well established methods for using antibodies in detection assays.

Example 3

Outline of Specification:

The application describes the isolation of a protein (SEQ ID NO: 3) which meets the novelty and inventive step (non-obviousness) requirements. Based upon the disclosed homology to known R-receptor amino acid sequences, there is no reason to doubt that the claimed receptor represents a new member of this protein family. The application describes methods of screening for compounds that activate this receptor. The application further discloses that different R-receptors are important in a wide variety of physiological processes, but does not disclose any particular biological or biochemical process in which this receptor is involved, except that its activation induces a cascade of second-messenger signals, similar to that of a G-protein coupled receptor.

The patent application specification includes a specific description of a series of screening procedures commensurate in scope with those recited in the claims. In particular, there is a description of a method of identifying or screening for agonists of this receptor, i.e., compounds that activate the claimed receptor, wherein the activated state is detected when a cascade of second-messenger signals occurs. There is no doubt that the skilled artisan could use the claimed R-receptor to identify (find) agonists.

In addition, the application discloses three working examples wherein compounds activating this receptor, namely X, Y, and Z were identified using the disclosed screening procedure.

The application provides no structural information for compounds other than X, Y, or Z or methods of making compounds other than X, Y, or Z.

Furthermore, although the receptor of SEQ ID NO: 3 was expressed in an animal cell, antibodies that recognize the receptor were not actually produced.

Claims:

1. An isolated and purified receptor the sequence of which consists of SEQ ID NO: 3.

35 U.S.C. § 101: Utility

See Example 1, claim 1 for a discussion of the relevant patentability considerations.

This claim does not meet the utility requirement of 35 U.S.C. § 101. In this example, the fact pattern indicates that there is no reason to doubt that the claimed protein is a member of the R-receptor family of proteins. Assignment to a prior art family of proteins is generally insufficient to meet the utility requirement unless such assignment would allow the artisan to assign a specific and substantial use to the new member of the protein family. The fact that the claimed receptor mediates signals by widespread pathways such as those associated with G-coupled protein receptor fails to cure this problem without some indication of the particular process with which the receptor is associated.

The rejection might be overcome with a showing of objective evidence that supports the position that one of ordinary skill in the art would recognize that each member of the R-receptor protein family would have been reasonably expected to have a particular specific and substantial function or activity or that the as-filed specification would have been sufficient to provide the artisan with an indication of a real world use.

35 U.S.C. § 112, first paragraph: Written Description

See Example 1, claim 1 for a discussion of the relevant patentability considerations.

This claim meets the requirement for an adequate written description of the claimed invention as required by 35 U.S.C. § 112, first paragraph. The scope of the claim is limited to a protein molecule whose primary structure is specifically disclosed.

35 U.S.C. § 112, first paragraph: Enablement

See Example 1, claim 1 for a discussion of the relevant patentability considerations.

This claim meets the enablement requirement for the "how to make" prong of 35 U.S.C. § 112, first paragraph. Given the primary protein sequence, the skilled artisan would have been able to have prepared the claimed protein.

However, this claim does not meet the requirement for the "how to use" prong of 35 U.S.C. § 112, first paragraph, because the disclosure does not teach a use that would meet the utility requirement of 35 U.S.C. § 101 (see comments below re: claim 2).

2. A method of identifying an agonist of the receptor of claim 1 comprising:
preparing a candidate compound,
contacting a cell which expresses said receptor on its surface with said candidate compound, and
determining whether said candidate compound activates the receptor of claim 1,
wherein a compound that activates the receptor of claim 1 is an agonist of said receptor.

35 U.S.C. § 101: Utility

This claim would not meet the utility requirement of 35 U.S.C. § 101. As noted above in the comments regarding claim 1, the fact pattern indicates that there is no reason to doubt that the claimed protein is a member of the R-receptor family of proteins. However, assignment to a prior art family of proteins is generally insufficient to meet the utility requirement unless such assignment would allow the artisan to assign a specific and substantial use to the new member of the protein family. In the case of the instant claim to a method of identifying an agonist, in the absence of an understanding of a specific and substantial use for the agonist, a method of identifying such would not comply with the requirements for utility.

The rejection might be overcome with a showing of objective evidence that supports the position that one of ordinary skill in the art would recognize that each member of the R-receptor protein family would have been reasonably expected to have a particular specific and substantial function or activity, or that there would be a specific and substantial use for the product identified by the claimed method.

35 U.S.C. § 112, first paragraph: Written Description

This method of identifying agonist compounds meets the requirement for an adequate written description as required by 35 U.S.C. § 112, first paragraph, because it is specifically noted that the specification teaches methods of screening for compounds that activate this receptor. That is, the activated state can be detected when a cascade of second-messenger signals occurs. Therefore, one skilled in the art would conclude that the applicant was in possession of such methods.

35 U.S.C. § 112, first paragraph: Enablement

This claim meets the requirements for “how to make” requirement of 35 U.S.C. § 112, first paragraph, since the specification specifically teaches methods of screening for compounds that activate the claimed receptor of claim 1.

However, the claim fails to meet the “how to use” requirement of 35 U.S.C. § 112, first paragraph, for reasons set forth above in the analysis of the compliance of the claimed invention with the requirements of 35 U.S.C. § 101.

3. An isolated and purified receptor agonist identified by the method of claim 2.

35 U.S.C. § 101: Utility

This claim would not meet the utility requirement of 35 U.S.C. § 101. As noted above in the comments regarding claim 1, the fact pattern indicates that there is no reason to doubt that the claimed protein is a member of the R-receptor family of proteins. However, assignment to a prior art family of proteins is generally insufficient to meet the utility requirement unless such assignment would allow the artisan to assign a specific and substantial use to the new member of the protein family. In the case of the instant claim to an agonist identified by the method of claim 2, there is no indication of the use to which the claimed agonist is to be put, therefore, the artisan would have to discover a use. Therefore, the claimed invention is not be supported by a substantial utility.

The rejection might be overcome with a showing of objective evidence that supports the position that one of ordinary skill in the art would recognize that each member of the R-receptor protein family would have been reasonably expected to have a particular specific and substantial function or activity, or that a specific and substantial purpose for agonizing such function would have been known to those of skill in the art.

35 U.S.C. § 112, first paragraph: Written Description

The claimed invention is drawn to a genus of agonist(s) identified by the method of claim 2 and the specification discloses at least some examples of the structure of compounds within the scope of what is claimed. However, there is no evidence that there is any *per se* structure/function relationship between the disclosed agonist compounds and any others that might be found using the claimed method. Structural identifying characteristics of the genus members are not disclosed. Therefore, the claimed invention is not supported by an adequate written description.

The rejection might be overcome with a showing of objective evidence that supports the proposition that the particularly disclosed receptor agonists were representative of the structure of the group of molecules that would be detected or identified by the claimed method.

35 U.S.C. § 112, first paragraph: Enablement

This claim fails to meet the enablement requirement for the “how to make” prong of 35 U.S.C. § 112, first paragraph. Since the instant fact pattern fails to indicate that a representative number of structurally related compounds is disclosed, the artisan would not know the identity of any nondisclosed compound falling within the scope of the instant claim and consequently would not have know how to make it. An assay for *finding* a product is not equivalent to a positive recitation of *how to make* a product. A rejection indicating that the claimed invention is only enabled for how to make those

compounds specifically disclosed would be appropriate.

Similarly, and for reasons set forth above in the analysis of the compliance of the claimed invention with the requirements of 35 U.S.C. § 101, the claimed methods fails to meet the requirements of "how to use" prong of 35 U.S.C. § 112, first paragraph.

4. (EPO) Use of a receptor agonist for the manufacture of a medicament for treating a disease treatable by said agonist, wherein said receptor agonist is identified by the method of claim 2.
   (USPTO) A method for the treatment of disease treatable by the agonist of claim 2, comprising administering to a host in need thereof a therapeutically effective amount of the agonist of claim 3.
   (JPO) Composition comprising a receptor agonist for use in treating a disease treatable by said agonist, wherein said receptor agonist is identified by the method of claim 2, as an active ingredient.

35 U.S.C. § 101: Utility

This claim does not meet the utility requirement of 35 U.S.C. § 101. The claimed invention is drawn to a method of treating an undisclosed disease. Since the fact pattern fails to establish what disease, if any, would be treatable by the agonist, the artisan would have no specific and substantial treatment to perform.

Objective evidence might overcome this rejection if it supported an assertion that one of ordinary skill in the art would recognize what disease(s) would have been able to have been treated with the claimed agonist.

35 U.S.C. § 112, first paragraph: Written Description

This method of treatment claim fails to meet the requirement for an adequate written description of the claimed invention as required by 35 U.S.C. § 112, first paragraph. There is insufficient descriptive support for the genus "agonist" as explained above. Further, the method requires treatment of an unspecified disease and no evidence indicates that a treatable disease was known to applicant. Therefore, the fact pattern indicates that the artisan was not in possession of the claimed method of use. In the absence of some understanding of the disease to be treated and which, if any, agonists could be used to treat said disease, the artisan would not have accepted that the applicant was in possession of the claimed method.

35 U.S.C. § 112, first paragraph: Enablement

This claim fails to meet the enablement requirement for the "how to make" prong of 35 U.S.C. § 112, first paragraph. Given that no treatable disease is disclosed nor any information as to how any par-

ticular undisclosed agonist would have been administered to treat any specific disease, the artisan would not have been able to have practiced the steps required by the claimed invention without undue experimentation.

Similarly, and for reasons set forth above in the analysis of the compliance of the claimed invention with the requirements of 35 U.S.C. § 101, the claimed method fails to meet the requirements of "how to use" prong of 35 U.S.C. § 112, first paragraph.

5. (EPO) Use of compound X for the manufacture of a medicament for treating a disease treatable by said compound.
   (USPTO) A method for treating a disease treatable by compound X comprising administering to a host in need thereof a therapeutically effective amount of compound X.
   (JPO) Composition comprising compound X for use in treating a disease treatable by said compound, as an active ingredient.

This claim fails to meet the collective requirements of 35 U.S.C. §§ 101, 112, first paragraph, written description and enablement for the same reasons as set forth above in the analysis of claim 4, except that compound X itself is adequately described, and that one skilled in the art would be able to make compound X based on the disclosure.

6. A monoclonal antibody which recognizes the receptor of claim 1.

35 U.S.C. § 101: Utility

This claim does not meet the utility requirement of 35 U.S.C. § 101. Given that there is no utility for the claimed receptor, there would be no specific and substantial reason to detect it with the claimed antibody or to use the antibody in any other manner.

The rejection might be overcome by a showing of objective evidence that supports the position that one of ordinary skill in the art would recognize that each member of the R-receptor protein family would have been reasonably expected to have a particular specific and substantial function or activity.

35 U.S.C. § 112, first paragraph: Written Description

This claim meets the requirement for an adequate written description of the claimed invention as required by 35 U.S.C. § 112, first paragraph. The scope of the claim is limited to an antibody that binds to a particularly recited protein. In view of the manner in which antibodies are made, it is generally accepted that if one is in possession of any particular protein sequence, one would also have been "in possession" of its antibody.

35 U.S.C. § 112, first paragraph: Enablement

This claim meets the enablement requirement for the "how to make" prong of 35 U.S.C. § 112, first paragraph. Given the primary protein structure to which an antibody is to be made, one would have been able to use routine and well known methods to prepare an antibody to such a target.

However, this claim does not meet the requirement for the "How to use" prong of 35 U.S.C. § 112, first paragraph, because the disclosure does not teach a use that would meet the utility requirement of 35 U.S.C. § 101.

Example 4:

Outline of Specification:

The application describes the isolation of a receptor (SEQ ID NO: 4) which meets the novelty and inventive step (non-obviousness) requirements as well as methods of screening for compounds that activate this receptor. The application further discloses that the receptor is useful for the treatment of obesity.

The patent application specification includes a specific description of a series of screening procedures commensurate in scope with those recited in the claims.

In addition, the application discloses three working examples wherein agonists of this receptor, i.e., compounds activating this receptor, namely X, Y, and Z were identified using the disclosed screening procedure.

Furthermore, the pharmacological mechanism involved in the treatment or inhibition of obesity by the activation of this receptor is described theoretically in the specification.

In addition, *in vivo* test data confirms that at least compound X is able to activate this receptor when administered to a host animal and such administration results in a reduction in total body weight of an art recognized model for obesity.

The application provides no structural information for compounds other than X, Y, or Z or methods of making compounds other than X, Y, or Z.

Furthermore, although the receptor of SEQ ID NO: 4 was expressed in an animal cell, antibodies that recognize the receptor were not actually produced.

Claims:

1. An isolated and purified receptor the sequence of which consists of SEQ ID NO: 4.

35 U.S.C. § 101: Utility

See Example 1, claim 1 for a discussion of the relevant patentability considerations.

This claim meets the utility requirement of 35 U.S.C. § 101. Only one specific, substantial, and credible utility is required to support the requirements of 35 U.S.C.

§ 101. In the instant case, the presence or absence of the receptor is useful in diagnostic methods relating to obesity.

35 U.S.C. § 112, first paragraph: Written Description

See Example 1, claim 1 for a discussion of the relevant patentability considerations.

This claim meets the requirement for an adequate written description of the claimed invention as required by 35 U.S.C. § 112, first paragraph. The scope of the claim is limited to a protein molecule whose primary structure is specifically disclosed.

35 U.S.C. § 112, first paragraph: Enablement

See Example 1, claim 1 for a discussion of the relevant patentability considerations.

This claim meets the "how to make" prong of the enablement requirement of 35 U.S.C. § 112, first paragraph. Given the primary protein sequence, the skilled artisan would have been able to prepare the claimed protein. The claim meets the "how to use" prong of 35 U.S.C. § 112, first paragraph, since the receptor's presence or absence may be used in diagnostic methods relating to obesity.

2. A method of identifying an agonist of the receptor of claim 1 comprising:
   preparing a candidate compound,
   contacting a cell which expresses said receptor on its surface with said candidate compound, and
   determining whether said candidate compound activates the receptor of claim 1,
   wherein a compound that activates the receptor of claim 1 is an agonist of said receptor.

35 U.S.C. § 101: Utility

This claim meets the utility requirement of 35 U.S.C. § 101 since the instant fact pattern indicates that agonist compounds that, by definition, activate their cognate molecules, would be potentially useful for the treatment of obesity.

35 U.S.C. § 112, first paragraph: Written Description

This method of identifying agonist compounds meets the requirement for an adequate written description as required by 35 U.S.C. § 112, first paragraph, because it is specifically noted that the specification teaches methods of screening for compounds that activate this receptor. Therefore, the person skilled in the art would conclude that the applicant was in possession of such methods.

35 U.S.C. § 112, first paragraph: Enablement

This claim also meets the requirements for how to make and use the claimed method of identifying agonist compounds since the specification specifically teaches methods of screening for compounds that activate the claimed receptor of claim 1.

3. An isolated and purified receptor agonist identified by the method of claim 2.

35 U.S.C. § 101: Utility

The claimed receptor agonist meets the requirement for utility as set forth in 35 U.S.C. § 101 for reasons set forth above in the analysis of claims 1 and 2.

35 U.S.C. § 112, first paragraph: Written Description

The claimed invention is drawn to a genus of agonist(s) identified by the method of claim 2 and the specification discloses at least some examples of the structure of compounds within the scope of what is claimed. Structural identifying characteristics of the agonist genus are not disclosed. There is no evidence that there is any *per se* structure/function relationship between the disclosed agonist compounds and any others that might be found using the claimed method. Therefore, the claimed invention is not supported by an adequate written description.

The rejection might be overcome by showing of objective evidence that supports the proposition that the particularly disclosed receptor agonists were representative of the structure of the group of molecules that would be detected or identified by the claimed method.

35 U.S.C. § 112, first paragraph: Enablement

This claim fails to meet the enablement requirement for the "how to make and use" prongs of 35 U.S.C. § 112, first paragraph for the full scope of what is claimed. Since the instant fact pattern fails to indicate that a representative number of structurally related compounds is disclosed, the artisan would not know the identity of a reasonable number of representative compounds falling within the scope of the instant claim and consequently would not have know how to make them. An assay for *finding* a product is not equivalent to a positive recitation of *how to make* a product. A rejection indicating that the claimed invention is only enabled for those compounds specifically disclosed would be appropriate.

4. (EPO) Use of a receptor agonist for the manufacture of a medicament for inhibiting obesity, wherein said receptor agonist is identified by the method of claim 2.
   (USPTO) A method for the treatment of obesity comprising administering to a host in need thereof a therapeutically effective amount of the agonist identified by the method of claim 2.

(JPO) Composition comprising a receptor agonist for use in treating obesity wherein said receptor agonist is identified by the method of claim 2, as an active ingredient.

35 U.S.C. § 101: Utility

This claim meets the utility requirement of 35 U.S.C. § 101 since the method is drawn to the treatment of a particular disease of real world relevance. In addition, based upon the instant fact pattern, there is no reason to question the assertion that one could potentially treat obesity with agonists to the claimed R-receptor.

35 U.S.C. § 112, first paragraph: Written Description

This method of treatment claim fails to meet the requirement for an adequate written description of the claimed invention as required by 35 U.S.C. § 112, first paragraph. There is insufficient descriptive support for the genus "agonist" as explained above. Further, the claimed invention is drawn to a method of treatment that requires the use of undisclosed agonists. In order to evidence possession of the claimed method, one would need demonstrate possession of its process steps which require the use of undisclosed compounds.

35 U.S.C. § 112, first paragraph: Enablement

This claim fails to meet the enablement requirement for the "how to make and use" prongs of 35 U.S.C. § 112, first paragraph for the full scope of what is claimed. Since the instant fact pattern fails to indicate that a representative number of structurally related compounds is disclosed, the artisan would not know the identity of a reasonable number of representative compounds falling within the scope of the instant claim and consequently would not have known how to make them. An assay for *finding* a product is not equivalent to a positive recitation of *how to make* a product. A rejection indicating that the claimed invention is only enabled for those compounds specifically disclosed would be appropriate.

5. (EPO) Use of compound X for the manufacture of a medicament for inhibiting obesity.
   (USPTO) A method for the treatment of obesity comprising administering to a host in need thereof a therapeutically effective amount of compound X.
   (JPO) Composition comprising compound X for use in treating obesity, as an active ingredient.

35 U.S.C. § 101: Utility

This claim meets the utility requirement of 35 U.S.C. § 101 since the method is drawn to the treatment of a particular disease of real world relevance. In addition, based upon the instant fact pattern, there is no reason to question the assertion that one could potentially treat obesity with agonists to the claimed R-receptor.

35 U.S.C. § 112, first paragraph: Written Description

This method of treatment claim meets the requirement for an adequate written description of the claimed invention as required by 35 U.S.C. § 112, first paragraph, since the claimed invention is drawn to treating a disclosed disorder using a disclosed and adequately described agonist.

35 U.S.C. § 112, first paragraph: Enablement

This claim meets the enablement requirement for the "How to make and use" prongs of 35 U.S.C. § 112, first paragraph since the claimed invention is drawn to treating a disclosed disorder using a disclosed agent.

6. A monoclonal antibody which recognizes the receptor of claim 1.

35 U.S.C. § 101: Utility

This claim meets the utility requirement of 35 U.S.C. § 101. Only one specific, substantial, and credible utility is required to support the requirements of 35 U.S.C.
§ 101. In the instant case, the presence of absence of the receptor is useful in diagnostic methods relating to obesity and an antibody could be used in such assays.

35 U.S.C. § 112, first paragraph: Written Description

This claim meets the requirement for an adequate written description of the claimed invention as required by 35 U.S.C. § 112, first paragraph. The scope of the claim is limited to an antibody that binds to a particularly recited protein. In view of the manner in which antibodies are made, it is generally accepted that if one is in possession of any particular protein sequence, one would also have been "in possession" of its antibody.

35 U.S.C. § 112, first paragraph: Enablement

This claim meets the enablement requirement for the "how to make" prong of 35 U.S.C. § 112, first paragraph. Given the primary protein structure to which an antibody is to be made, one would have been able to use routine and well known methods to prepare an antibody to such a target.

This claim meets the requirement for the "how to use" prong of 35 U.S.C. § 112, first paragraph, since there were well established methods for using antibodies in detection assays.

ANNEX 2: Comments of the EPO

QUESTIONNAIRE FOR COMPARATIVE STUDY ON REACH THROUGH CLAIMS
- EPO comments, summary

revised version 05-10-2001

Case 1:	Ind. Appln	Sufficiency	Clarity/Support
Claim 1 (Receptor)	-	+/-	+
Claim 2 (Screen.-meth.)	-	-	+/-
Claim 3 (Agonist)	-	-	-
Claim 4 (Use of agon.)	-	-	-
Claim 5 (MoAb)	-	+/-	+

Case 2:	Ind. Appln	Sufficiency	Clarity/Support
Claim 1 (Receptor)	+	+	+
Claim 2 (Screen.-meth.)	+	+	+
Claim 3 (Agonist)	+	-	-
Claim 4 (Use of agon.)	+	-	-
Claim 5 (MoAb)	+	+	+

Case 3:	Ind. Appln	Sufficiency	Clarity/Support
Claim 1 (Receptor)	-	+/-	+
Claim 2 (Screen.-meth.)	-	+/-	+
Claim 3 (Agonist)	-	-	-
Claim 4 (Use of agon.)	-	-	-
Claim 5 (use of spec. agon)	-	-	-
Claim 6 (MoAb)	-	+/-	+

Case 4:	Ind. Appln	Sufficiency	Clarity/Support
Claim 1 (Receptor)	+	+	+
Claim 2 (Screen.-meth.)	+	+	+
Claim 3 (Agonist)	+	+/-(scope)	+/-(scope)
Claim 4 (Use of agon.)	+	+/-(scope)	+/-(scope)
Claim 5 (use of spec. agon)	+	+	+
Claim 6 (MoAb)	+	+	+

+: no objection
- : objection(s) mainly **in addition to** **"**Lack of Inventive Step**"**!

QUESTIONNAIRE FOR COMPARATIVE STUDY ON REACH THROUGH CLAIMS

- EPO comments

1). THE RECEPTORS (claim 1 of cases 1-4)

1.1. In **cases 1-4**, the receptors are characterized by their sequence, and they have been expressed in animal cells.

1.2. In **cases 2 and 4**, the specific function has been described.

1.3. **=> no objection in cases 2 and 4;** the requirements of Arts. 56(Inventive Step), 57(Industrial Application), 83(Disclosure), 84(Clarity and Support) are met.

1.4. In **cases 1 and 3**, a rather vague function has been inferred from homology considerations: The claimed compounds are putative members of the vast family of "R-receptors" which are involved in a wide variety of physiological processes.

1.5. ==> Objections in cases 1 and 3:

Inventive Step (Art. 56): NO
Even though the outline for examples 1 and 3 states that the protein (SEQ ID NO:1) meets the inventive step and non-obviousness requirements, the EPO position is that such a claim cannot meet the requirements of **Inventive Step** (the other objections, as detailed further below, will however be made additionally if considered appropriate):

Prima facie, the routine provision of further sequences having the same general function as the known prior art sequences of closely related structure is **not inventive**. The **structural non-obviousness** is not a reason to accept an inventive step; sequences as well as all other chemical compounds should **solve a technical problem** in a non-obvious manner to be recognised as inventive.

Industrial application (~"utility"; Art. 57/R23(e)(3)/R27(1)(f)/Guidelines C-IV 4.6): NO
The function indicated in cases 1 and 3 is vague and heterogeneous: it includes a large variety of different physiological roles. Without the sequence (SEQ ID NO:1) being assigned to a particular (specific) function, it would not be suitable for industrial application.

Sufficiency of disclosure: (~"enablement"; Art. 83/Rule 27/Guidel. C-II 4ff): YES/NO
There is no doubt that the receptor protein can be prepared, in this respect it meets the requirements of sufficiency. However, since the specific function has not been disclosed in cases 1 and 3, it can be debated whether it would be an undue burden to perform the invention over the whole area (i.e. including the determination the specific function of the claimed receptor). This is however rather a problem that should be dealt with under "lack of inventive step" (supra).

Clarity and Support (Art. 84/Rule 29/Guidelines C-III): YES
The claims to the receptor are **clear and concise** (C-III 4ff and C-III 5), since the latter is identified by its sequence, which is a part of the description.
(NB: There is however no support in the description for the verification of assumptions

concerning the specific function, which would be necessary to overcome more straightforward objections under Arts. 56 and 57).

Possibilities to overcome the objections
Case 1: No obvious possibility; amendments are very likely to violate Art. 123(2) EPC.
Case 3: No obvious possibility, unless in the context of compounds X,Y,Z there is a more concrete indication of function.

2). THE METHODS FOR IDENTIFYING AGONISTS (claim 2 of cases 1-4)

2.1. In **cases 1 and 2**, there is only a general description of screening methods, but no working example.

2.2. In **cases 3 and 4**, ligands to the receptors have been isolated on the basis of the claimed method.

2.3. In **cases 2 and 4, but not 1 and 3**, the receptors have been found to meet the criteria of Arts. 56, 57, 83 and 84.

2.4. ==> no objections in cases 2 and 4

2.5. ==> objections in cases 1 and 3:

Inventive Step:
Cases 1 and 3: NO
logical consequence of item 1.5: no technical problem is solved if the specific function of the receptor and the agonists is unknown.
analogous to item 1.5
Cases 2 and 4: YES

Industrial Application:
Cases 1 and 3: NO
The receptor itself is not industrially applicable, because it has no specific function. It follows that there can be no industrial applicability for the methods of identifying agonists that are supposed to stimulate an unknown function.
Cases 2 and 4: YES
In view of the proven pharmaceutical relevance of the receptor, methods for identifying agonists are obviously industrially applicable.

Sufficiency:
Case 1: NO
The specific function of the receptor has not been disclosed. It would be an undue burden to determine the specific function that is to be stimulated by the agonist, which is a prerequisite for the identification of agonists.
Case 3: YES/NO
3 candidate compounds have been isolated that bind to the receptor and trigger a cascade of second messenger signals. It can therefore be accepted that compounds X,Y and Z are agonists, and that the method is suitable to detect agonists.

However, since the specific function has not been disclosed, it can be debated whether it would be an undue burden to perform the invention over the whole area. This is however a problem that should be dealt with under "lack of inventive step" (see item 1.5).

Cases 2 and 4: YES

In both cases, the receptor has been obtained in pure and active form; it would appear that methods for measuring the function of the receptor have also been disclosed in the application. On this basis, there appears to be no known obstacle to setting up a method for identifying agonists, either on the basis of routine procedures as described in the application (case 2), or by following the examples of case 4.

Clarity and Support:

- Clarity:

Cases 1-4: YES

- Support:

Case 1: NO

In case 1, there is no sufficient support for the function of the receptor, its activation, and the measurement of the activation.

Case 3: YES

A screening method has been performed, and 3 candidate compounds have been isolated that are very likely to be aginists, although the specific function is unknown.

Cases 2 and 4: YES

Possibilities to overcome the objections

Cases 1 and 3: As under item 1.5: No obvious possibility; amendments are very likely to violate Art. 123(2) EPC.

3). THE AGONISTS IDENTIFIED BY THE METHOD OF CLAIM 1 (claim 3 of cases 1-4)

3.1. In **cases 1 and 2**, no agonist has been isolated.

3.2. In **cases 3 and 4**, only three compounds that bind to the receptor of claim 1 have been isolated and characterized.

3.3. **==> objections in cases 1-4**:

All claims No. 3 will already be objected to at the **search stage**:

no search will be carried out for compounds which are **only** defined by the method for their identification (Guidelines B-III 3.7): No special search effort for unduly wide or speculative claims, for subject-matter which is not sufficiently disclosed (Art. 83 EPC) or not supported by the description (Art. 84 EPC). A meaningful search is not possible (B-VIII, 6), since it would require a minimum of structural information: The functional feature "binding to a receptor" may be an inherent known or unknown feature of any known and unknown organic or inorganic compound (in cases 3 and 4, a partial search for the compounds X,Y,Z is of course possible).

Industrial application:

Case 1: NO

An objection under Lack of Industrial Application is possible (a compound that has not been disclosed cannot be made and used in any kind of industry), but the main objection will be under Lack of Support.

Case 2: YES
Although the same argument ("a compound that has not been disclosed cannot be made and used in any kind of industry") could also be made in case 2, it can also be argued here that the person skilled in the art would know that there is a potential application of agonists in the treatment of obesity. The question "Industrial application, yes or no" has however no practical relevance in this case, since the Lack of Support is so striking.
Case 3: NO
Analogous to item 2.5.
Case 4: YES
For the assessment of industrial application, the scope is not taken into consideration.
The compounds of examples X,Y,Z fulfil the requirements.

Sufficiency:
Cases 1-2: NO
(Note however that Art. 83 will mainly be used if Art. 84 is no longer available, i.e. in opposition):
There is no sufficient disclosure of the technical solution to the problem, i.e. the structurally defined compounds (Rule 27(1)(c); Guidelines C-II 4.1, 4.5). It would be an undue burden to isolate and to characterize possibly binding compounds without any clue to their chemical structure (Guidelines C-II 4.9), or to test each and every known and future compound from all areas of organic and inorganic chemistry whether it falls within the scope of the claim.
Case 3:
Compounds X,Y,Z: NO
Although the compounds as such are sufficiently disclosed to be prepared, there is no sufficient indication of the specific function of the agonists. The term "agonist" implies that the claim to the compound is linked to a functional definition. In such a case, the specific function has to be indicated, in order to fulfill the requirements on sufficiency of disclosure.
General scope: NO
In the absence of any indication of a general formula for a larger group of compounds that plausibly act as agonists, the motivation for cases 1 and 2 applies.
Case 4:
Compounds X,Y,Z: YES
General scope: NO
In the absence of any indication of a general formula for a larger group of compounds that plausibly act as agonists, the motivation for cases 1 and 2 applies for the general scope of claim 3.

Clarity and Support
- Clarity:
Cases 1-2: NO
Claim 3 does not include the technical feature (i.e. the structure) which is essential for the technical effect (binding to the receptor, T32/82).
Characterisation of a compound only by parameters is not allowed, as no meaningful comparison with the prior art can be made (Guidelines C-III 4.7a).
Attempts to define an invention by the result to be achieved (i.e. here: the results of a ligand-binding experiment) are not allowed (C-III 4.7)
Case 3:
X,Y,Z: NO
Although the compounds themselves are clearly identified, the functional aspect "agonist"

is not clear. The selective binding of a compound to a receptor, without indicating the specific function of the agonist does not allow to assess the contribution to the state of the art (see the recent decision T241/95).
General scope: NO
In the absence of any indication of a general formula for a larger group of compounds that plausibly act as agonists, the motivation for cases 1 and 2 applies.
Case 4:
X,Y,Z: YES
Compounds X,Y,Z are clearly defined by their formula.
General scope of claim 3: NO
See the discussion of cases 1 and 2.

- <u>Support:</u>
Cases 1-3: NO
In order to comply with the requirement of Art. 84, there must be sufficient support of technical character in the description that allows to extend the particular teaching of the description to the whole field claimed (C-III 6.3).
The functional feature "binding" is not a technical feature that allows to distinguish the claimed group of compounds from prior art compounds. It is not possible for the person skilled in the art to recognize the members of the claimed group, because the functional feature only indicates what the compound does, and not what it is. The definition by the function only is therefore merely the definition by a result, and not as required the indication of the technical feature that is necessary to achieve the result (supra, C-III 4.7).
Art. 84 and Rule 27(1)(c, e) require a technical description of the invention, and not the indication of a functional property that one might observe if he made that invention.
Case 4:
X,Y,Z: YES
General scope of claim 3: NO
see the discussion of cases 1 - 3.

<u>Possibilities to overcome the objections</u>
Cases 1 - 3: no obvious possibility
Case 4: Restriction to X,Y,Z

4). MEDICAL APPLICATION OF AGONISTS IN GENERAL, OBTAINED BY THE METHOD OF CLAIM 3 (claim 4 of cases 1-4)

Cases 1-4:
Motivation as under item 3: if a compound is not industrially applicable (or sufficiently supported, or disclosed), the medical application of said compounds suffers *a fortiori* from the same deficiencies.

5). MEDICAL APPLICATION OF DEFINED AGONISTS (claim 5 of cases 3 and 4)

Case 3: Motivation in line with items 3 and 4. Unless a specific disease is known, claims relating to the treatment of the disease do not fulfil the requirements of industrial application, clarity, support in the description, and disclosure.

Case 4: no objection

6). MONOCLONAL ANTIBODIES AGAINST THE RECEPTORS OF CLAIM 1 (claim 5 in cases 1 and 2; claim 6 in cases 3 and 4)

Inventive step:
Cases 1 and 3: NO
logical consequence of item 1
Cases 2 and 4: YES

Industrial Application :
Cases 1 and 3: NO
logical consequence of item 1. There seems to be no industrial application for an antibody against a target which has itself no industrial application.
Cases 2 and 4: YES
The industrial application of an antibody against a receptor with known properties is obvious.

Sufficiency of disclosure:
cases 1 and 3: YES/NO
There is no doubt that an antibody can be made, once the receptor protein has been prepared, in this respect it meets the requirements of sufficiency. However, since the specific function of the receptor has not been disclosed in cases 1 and 3, it can be debated whether it would be an undue burden to determine the specific function for the antibody.
Cases 2 and 4: YES
The general process of obtaining antibodies has become routine. The person skilled in the art knows what to do with an antibody against a receptor with specific function.

Clarity and Support
Cases 1-4: YES
The claims to an antibody are clear and concise, if the target has been sufficiently defined. The term "antibody" implies a structural information and selects a certain genus of compounds. Antibodies are traditionally defined by their target. The combination of target-specificity with the restriction to a certain genus of compounds makes the claim searchable and clear. The general process for obtaining antibodies has become routine. The support in the description would be considered as sufficient.
(There is however no support in the description for the verification of assumptions concerning the specific function of the receptor and consequently of the antibody, see item 1).

CONCERNING THE CLAIMS DRAFTED TO ANTIBODIES:
Note however that in all four cases there appear to exist receptor families of closely related structure. In order to distinguish the antibodies of cases 1-4 from potentially existing prior art antibodies against related compounds, which may cross-react with

the present antibodies, it may become necessary to restrict the scope of the claims to **specific** antibodies, in order to overcome a novelty objection. There seems to be no basis in the description as filed for such an amendment.

ANNEX 3: Comments of the JPO

1. Summary of the Comments of the JPO

		Case 1	Case 2	Case 3	Case 4
Method used in considering function of receptor		based on homology search methods	based on experimental methods	based on homology search methods	based on experimental methods
Knowledge of the relationship between receptor and a specific disease (biological function)		unknown	confirmed	unknown	confirmed
Working example of claimed screening method		none	none	described	described
Receptor protein	Clarity	yes	yes	yes	yes
	Enablement	no	yes	no	yes
	Industrial Applicability	no	yes	no	yes
Screening method	Clarity	no	yes	yes	yes
	Enablement	no	yes	no	yes
	Industrial Applicability	no	yes	no	yes
Receptor agonist (activating compound)	Clarity	no	no	no	no
	Enablement	no	no	no	no
	Industrial Applicability	no	yes	no	yes
Pharmaceutical composition comprising receptor agonist (activating compound)	Clarity	no	no	no	no
	Enablement	no	no	no	no
	Industrial Applicability	no	yes	no	yes
Pharmaceutical composition comprising specific agonist (activating compound)	Clarity			no	yes
	Enablement			no	yes
	Industrial Applicability			no	yes
Monoclonal antibody recognizing receptor	Clarity	yes	yes	yes	yes
	Enablement	no	yes	no	yes
	Industrial Applicability	no	yes	no	yes

2. Detailed Comments

Case 1

Claim 1 [Receptor protein]

Q1) [Clarity: Yes] The receptor is specified by its amino acid sequence, and therefore is clear.

[Enablement: No] Even if the claimed receptor, from its homology to known R-receptor amino acid sequences, is considered to belong to the R-receptor family, the person skilled in the art could still not understand the relationship between the claimed receptor and any specific biological function or disease, even upon consideration of common general technical knowledge.

Therefore, the claim lacks enablement ,since the person skilled in the art could not understand "how to use" the receptor. It would require undue experimentation to perform such an invention.

Q2) [Industrial Applicability: No] The claim lacks industrial applicability, since the application does not indicate how the receptor is industrially applied.

Q3) [Other Comments] No obvious possibility to overcome reason for refusal, at least for lack of enablement.

Claim 2 [Screening method]

Q1) [Clarity: No] The claim lacks clarity, since the specification only gives a vague and general description of screening procedures, and it is unclear to the person skilled in the art, whatever conceivable changes in the experimental system would be available as the criteria of judgement, in choosing a receptor agonist (activating compound), even taking into consideration common general technical knowledge.

[Enablement: No] The claim lacks enablement as well, since the person skilled in the art, cannot understand, and therefore cannot use the above criteria of judgement, in choosing a receptor agonist (activating compound), even taking into consideration common general technical knowledge.

Furthermore, the claim lacks enablement from a different viewpoint, because in this case, the specific function of the claimed receptor is unknown, and therefore the person skilled in the art cannot easily understand the how to actually use any screening method utilizing said receptor. It would require undue experimentation to perform such an invention.

Q2) [Industrial Applicability: No] The claim also lacks industrial applicability, since the application does not disclose how to apply the receptor in an industrial way.

Q3) [Other Comments] No obvious possibility to overcome reason for refusal, at least for lack of enablement.

Claim 3 [Receptor agonist (activating compound)]

Q1) [Clarity: No] The claim lacks clarity, since the agonist is a compound specified by its function or property, and we cannot say that the person skilled in the art can easily formulate a specific compound from its function or property, even upon consideration of common general technical knowledge.

[Enablement: No] The claim lacks enablement, since the application does not disclose a specific use of the compound, and the person skilled in the art cannot know "how to use" it.

Furthermore, the claim also lacks enablement because there is no disclosure of specific chemical structures, which may be obtained through working examples, or any other matter which would serve as a clue to obtain such a compound. There is neither any support to whether such compound is actually obtainable. It would require undue experimentation to perform such an invention.

Q2) [Industrial Applicability: No] The claim also lacks industrial applicability, since the application does not disclose how to apply the receptor agonist (activating compound) in an industrial way.

Q3) [Other Comments] No obvious possibility to overcome reason for refusal, at least for lack of enablement.

Claim 4 [Pharmaceutical composition comprising receptor agonist (activating compound)]

Q1) [Clarity: No] The claim lacks clarity, because when the receptor agonist (activating compound) is unclear, a pharmaceutical composition comprising such agonist (activating compound) would also become unclear.

[Enablement: No] The claim also lacks enablement, because the person skilled in the art cannot understand how to obtain a specific agonist (activating compound), and what sort of disease-treating composition the compound should be used to manufacture, even upon consideration of general common technical knowledge. It would require undue experimentation to perform such an invention.

Q2) [Industrial Applicability: No] If the person skilled in the art cannot understand how to industrially apply the receptor agonist (activating compound), he/she could not under-

stand how to industrially apply a pharmaceutical composition comprising said agonist (activating compound). Thus, the claim lacks industrial applicability.

Q3) [Other Comments] See comments concerning claim 3.

Claim 5 [Anti-receptor monoclonal antibody]

Q1) [Clarity: Yes] The claimed monoclonal antibody is specified by the antigen it recognizes. This is a common way to specify a subject matter in this technical field. Therefore, if the antigen is clear, a monoclonal antibody specified by the antigen is also considered clear.

[Enablement: No] Since the person skilled in the art cannot understand how to use the receptor, he/she also cannot understand how to use a monoclonal antibody recognizing the receptor, and thus, the claim lacks enablement .

Q2) [Industrial Applicability: No] Since the claim for the receptor lacks industrial applicability, a monoclonal antibody recognizing the receptor also violates the same requirement.

Case 2

Claim 1 [Receptor protein]

Q1) [Clarity: Yes] The receptor is specified by its amino acid sequence, and therefore is clear.

[Enablement: Yes] The specification discloses the relationship between the receptor and a specific disease, and therefore, a use, such as an antigen to produce diagnostic antibodies can be recognized to the person skilled in the art. Therefore, the person skilled in the art can understand how to use the receptor. Furthermore, since the receptor is actually produced, it is assumed to be obtainable by conventional methods. Therefore, the claim complies with the enablement requirement.

Q2) [Industrial Applicability: Yes] The claim also meets industrial applicability, since the person skilled in the art can recognize a way to industrially apply the receptor.

Claim 2 [Screening method]

Q1) [Clarity: Yes] In this case, the description provides general reference toward standard screening methods. Although the description does not provide working examples, the description teaches a method for measuring the biochemical and binding activity of the specific receptor, and the person skilled in the art can understand what is claimed.

[Enablement: Yes] The claim complies with enablement, since the person skilled in

the art can understand how to perform the screening method, since the description teaches a method for measuring the biochemical and binding activity of the specific receptor.

Q2) [Industrial Applicability: Yes] The claim meets industrial applicability, since if there would be such a screening method, it would be useful for the discovery of a novel anti-obesity compound.

Claim 3 [Receptor agonist (activating compound)]

Q1) [Clarity: No] The claim lacks clarity, since the agonist is a compound specified by its function or property, and we cannot say that the person skilled in the art can easily formulate a specific compound from its function or property, even upon consideration of common general technical knowledge.

[Enablement: No] The claim also lacks enablement because there is no disclosure of specific chemical structures, which may be obtained through working examples, or any other matter which would serve as a clue to obtain such a compound. There is neither any support to whether such compound is actually obtainable. It would require undue experimentation to perform such an invention.

Q2) [Industrial Applicability: Yes] The claim meets industrial applicability, since if there would be such an agonist (activating compound), it would be useful for the manufacture of a novel anti-obesity drug.

Q3) [Other Comments] No obvious possibility to overcome reason for refusal, at least for lack of enablement.

Claim 4 [Pharmaceutical composition comprising receptor agonist (activating compound)]

Q1) [Clarity: No] The claim lacks clarity, because when the receptor agonist (activating compound) is unclear, a pharmaceutical composition comprising such agonist (activating compound) would also become unclear.

[Enablement: No] The claim also lacks enablement, because the person skilled in the art cannot understand how to obtain a specific agonist (activating compound), even upon consideration of general common technical knowledge. It would require undue experimentation to perform such an invention.

Q2) [Industrial Applicability: Yes] The application discloses that the composition can be used as an anti-obesity drug, and therefore is industrially applicable.

Claim 5 [Anti-receptor monoclonal antibody]

Q1) [Clarity: Yes] The claimed monoclonal antibody is specified by the antigen it recognizes. This is a common way to specify a subject matter in this technical field. Therefore, if the antigen is clear, a monoclonal antibody specified by the antigen is also considered clear.

[Enablement: Yes] If an antigen protein is obtainable, a monoclonal antibody that simply recognizes the antigen is also considered obtainable, using conventional methods. And if the person skilled in the art can understand how to make and use the receptor, he/she can also understand how to use a monoclonal antibody recognizing the receptor. In this case, both requirements are met, and thus, the claim meets enablement.

Q2) [Industrial Applicability: Yes] Since the claim for the receptor meets industrial applicability, a monoclonal antibody recognizing the receptor also meets the same requirement.

Case 3

Claim 1 [Receptor protein]

Q1) [Clarity: Yes] The receptor is specified by its amino acid sequence, and therefore is clear.

[Enablement: No] Even if the claimed receptor, from its homology to known R-receptor amino acid sequences, is considered to belong to the R-receptor family, the person skilled in the art could still not understand the relationship between the claimed receptor and any specific biological function or disease, even upon consideration of common general technical knowledge.

Therefore, the claim lacks enablement , as the person skilled in the art could not understand "how to use" the receptor. It would require undue experimentation to perform such an invention.

Q2) [Industrial Applicability: No] The claim lacks industrial applicability, since the application does not indicate how the receptor is industrially applied.

Q3) [Other Comments] No obvious possibility to overcome reason for refusal, at least for lack of enablement.

Claim 2 [Screening method]

Q1) [Clarity: Yes] The claim meets clarity, since it is clear to the person skilled in the art,

based on the working example described in the application, whatever conceivable changes in the experimental system would be available as the criteria of judgement, in choosing a receptor agonist (activating compound).

[Enablement: No] The person skilled in the art can understand, based on the working example described in the application, whatever conceivable changes in the experimental system would be available as the criteria of judgement, in choosing a receptor agonist (activating compound).

However, the claim lacks enablement, because in this case the specific function of the claimed receptor is unknown, and therefore the person skilled in the art cannot easily understand how to actually use any screening method utilizing said receptor. It would require undue experimentation to perform such an invention.

Q2) **[Industrial Applicability: No]** The claim also lacks industrial applicability, since the application does not disclose how to apply the receptor in an industrial way.

Q3) **[Other Comments]** No obvious possibility to overcome reason for refusal, at least for lack of enablement.

Claim 3 [Receptor agonist (activating compound)]

Q1) **[Clarity: No]** The claim lacks clarity, since the agonist is a compound specified by its function or property, and we cannot say that the person skilled in the art can easily formulate a specific compound from its function or property, even upon consideration of common general technical knowledge.

[Enablement: No] The claim lacks enablement, since the application does not disclose a specific use of the compound, and the person skilled in the art cannot know "how to use" it.

Furthermore, the claim also lacks enablement because, other than the compounds obtained in the working examples, there is no disclosure of specific chemical structures, or any other matter which would serve as a clue to obtain such a compound. Therefore, it would require the person skilled in the art to perform undue experimentation to obtain such a compound, having a basic structure other than the structures of the compounds obtained in the working examples.

Q2) **[Industrial Applicability: No]** The claim also lacks industrial applicability, since the application does not disclose how to apply the receptor agonist (activating compound) in an industrial way.

Q3) **[Other Comments]** No obvious possibility to overcome reason for refusal, at least for

lack of enablement.

Claim 4 [Pharmaceutical composition comprising receptor agonist (activating compound)]

Q1) [Clarity: No] The claim lacks clarity, because when the receptor agonist (activating compound) is unclear, a pharmaceutical composition comprising such agonist (activating compound) would also become unclear.

[Enablement: No] The claim also lacks enablement, because the person skilled in the art cannot understand how to obtain a specific agonist (activating compound) other than the compounds obtained in the working examples, and what sort of disease-treating composition the compound should be used to manufacture, even upon consideration of general common technical knowledge. It would require undue experimentation to perform such an invention.

Q2) [Industrial Applicability: No] In this case, the claim lacks industrial applicability as well.

Q3) [Other Comments] No obvious possibility to overcome reason for refusal, at least for lack of enablement.

Claim 5 [Pharmaceutical composition comprising specific compounds]

Q1) [Clarity: No] Since the specific function (e.g., its relationship to a specific disease) of the receptor is not disclosed, the claim referring to a "disease treatable by the agonist" of the said receptor is unclear.

[Enablement: No] The person skilled in the art cannot understand what sort of disease-treating composition the compound should be used in manufacturing, even upon consideration of general common technical knowledge.

Q2) [Industrial Applicability: No] In this case, the claim also lacks industrial applicability.

Claim 6 [Anti-receptor monoclonal antibody]

Q1) [Clarity: Yes] The claimed monoclonal antibody is specified by the antigen it recognizes. This is a common way to specify a subject matter in this technical field. Therefore, if the antigen is clear, a monoclonal antibody specified by the antigen is also considered clear.

[Enablement: No] Since the person skilled in the art cannot understand how to use the receptor, he/she also cannot understand how to use a monoclonal antibody recognizing the receptor, and thus, the claim lacks enablement .

Q2) [Industrial Applicability: No] Since the claim for the receptor lacks industrial applicability, a monoclonal antibody recognizing the receptor also lacks industrial applicability.

Case 4

Claim 1 [Receptor protein]

Q1) [Clarity: Yes] The receptor is specified by its amino acid sequence, and therefore is clear.

[Enablement: Yes] The relationship between the claimed receptor and a specific biological function or disease is disclosed in the application, and a screening method for obtaining anti-obesity compounds is also described and supported. The receptor is also actually produced. Therefore, the person skilled in the art could understand how to make and use the receptor. Thus, the claim meets enablement.

Q2) [Industrial Applicability: Yes] In this case, the claim meets industrial applicability.

Claim 2 [Screening method]

Q1) [Clarity: Yes] The claim meets clarity, since it is clear to the person skilled in the art, based on the working example described in the application, whatever conceivable changes in the experimental system would be available as the criteria of judgement, in choosing a receptor agonist (activating compound).

[Enablement: Yes] The person skilled in the art can understand, based on the working example described in the application, whatever conceivable changes in the experimental system would be available as the criteria of judgement, in choosing a receptor agonist (activating compound).

Furthermore, since the relationship between the claimed receptor and a specific disease is disclosed, the person skilled in the art can easily understand "how to use" the screening method utilizing said receptor. Therefore, the claim meets enablement.

Q2)[Industrial Applicability: Yes] In this case, the claim also meets industrial applicability, since it is clear from the specification how to apply the receptor in an industrial way.

Claim 3 [Receptor agonist (activating compound)]

Q1) [Clarity: No] The claim lacks clarity, since the agonist is a compound specified by its function or property, and we cannot say that the person skilled in the art can easily formulate a specific compound from its function or property, even upon consideration of common general technical knowledge.

[Enablement: No] The claim also lacks enablement because, other than the compounds obtained in the working examples, there is no disclosure of specific chemical structures, or any other matter which would serve as a clue to obtain such a compound. Therefore, it would require the person skilled in the art to perform undue experimentation to obtain such a compound, having a basic structure other than the structures of the compounds obtained in the working examples.

Q2) [Industrial Applicability: Yes] The claim meets industrial applicability, since if there would be such an agonist (activating compound), it would be useful for the manufacture of a novel anti-obesity drug.

Q3) [Other Comments] A restriction of the agonists (activating compounds) to the compounds which can be made by the person skilled in the art according to the description and considering the common general knowledge at the time of filing, would overcome the reason for refusal concerning lack of enablement. However, amendments must be made within the scope of the original specification (Patent Law Sec.17 bis).
Restriction to compounds X,Y,Z, which can be made by the person skilled in the art according to the description and considering the common general knowledge, will overcome the reasons for rejection above in this Case.

Claim 4 [Pharmaceutical composition comprising receptor agonist (activating compound)]

Q1) [Clarity: No] The claim lacks clarity, because when the receptor agonist (activating compound) is unclear, a pharmaceutical composition comprising such agonist (activating compound) would also become unclear.
[Enablement: No] The claim also lacks enablement, because the person skilled in the art cannot understand how to obtain a specific agonist (activating compound) other than the compounds obtained in the working examples, even upon consideration of general common technical knowledge. It would require undue experimentation to perform such an invention.

Q2) [Industrial Applicability: Yes] The application discloses that the composition can be used as an anti-obesity drug, and therefore is industrially applicable.

Q3) [Other Comments] See discussion in claim 3.

Claim 5 [Pharmaceutical composition comprising specific compounds]

Q1) [Clarity: Yes] A composition comprising specific compounds obtained from working

examples is clear.

[Enablement: Yes] The person skilled in the art can understand what sort of disease-treating composition the compound should be used to manufacture, and furthermore, the effect of the compounds are supported by pharmacological data.

Q2) [Industrial Applicability: Yes] The application discloses that the composition can be used as an anti-obesity drug, and therefore is industrially applicable.

Claim 6 [Anti-receptor monoclonal antibody]

Q1) [Clarity: Yes] The claimed monoclonal antibody is specified by the antigen it recognizes. This is a common way to specify a subject matter in this technical field. Therefore, if the antigen is clear, a monoclonal antibody specified by the antigen is also considered clear.

[Enablement: Yes] If an antigen protein is obtainable, a monoclonal antibody that simply recognizes the antigen is also considered obtainable, using conventional methods. And if the person skilled in the art can understand how to make and use the receptor, he/she can also understand how to use a monoclonal antibody recognizing the receptor. In this case, both requirements are met, and thus, the claim meets enablement.

Q2) [Industrial Applicability: Yes] In this case, the claim also meets industrial applicability.